CORRECTED JOINT APPENDIX VOLUME II (382-574)

No. 24-1714

In the United States Court of Appeals for the Federal Circuit

TRANSGENDER AMERICAN VETERANS ASSOCIATION,

Petitioner.

v.

SECRETARY OF VETERANS AFFAIRS,

Respondent.

Appeal of denial of petition for rulemaking by the Department of Veterans Affairs

Michael J. Wishnie

Counsel of Record

VETERANS LEGAL SERVICES

CLINIC

JEROME N. FRANK LEGAL

SERVICES ORGANIZATION

YALE LAW SCHOOL

P.O. Box 209090

New Haven, CT 06520-9090

(203) 432-4800

michael.wishnie@ylsclinics.org

Counsel for Petitioner

TABLE OF CONTENTS

1.	Letter from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Counsel, Transgender American Veterans Association (February 22, 2024)
2.	Petition for Rulemaking to Promulgate Regulations Governing Provision of Sex Reassignment Surgery to Transgender Veterans, with attachments (May 9, 2016)
3.	U.S. Department of Veterans Affairs, RIN 2900-AP69, "Removing Exclusion of Gender Alterations from the Medical Benefits Package" (Spring 2016)
4.	U.S. Department of Veterans Affairs, "Economic Impact Analysis for RIN 2900-AP69, Removing Gender Alterations Restriction from the Medical Benefits Package" (July 29, 2016)
5.	Letter from Members of the House of Representatives to the Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, (September 12, 2016)
6.	Letter from Members of the Senate to the Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs (September 12, 2016) Appx102
7.	Letters from the Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, to Members of Congress (November 10, 2016) Appx105
8.	The American College of Obstetrician and Gynecologists, "America's Frontline Physicians Urge Trump Administration to Protect Transgender Patients and Women's Reproductive Health" (May 28, 2019)Appx152
9.	Message from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Employees, U.S. Department of Veterans Affairs (February 23, 2021)

10.	Memo from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, "Services for LGBT Beneficiaries and Employees" (February 23, 2021)
11.	The Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, "Decision Memorandum: Removal of Gender Alterations Exclusion from VA Medical Benefits Package" (June 11, 2021)Appx158
12.	Remarks by the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, Orlando Veterans Affairs Healthcare System's 11th Annual Pride Month Celebration (June 19, 2021)
13.	Conclusion of EO 12866 Regulatory Review, RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs (September 7, 2022) Appx163
14.	Entry RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs (Fall 2022)
15.	Remarks by the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Disabled American Veterans (February 26, 2023) Appx165
16.	Letter from Kimberly M. Mitchell, Director, Veteran Service Organization Liaison, U.S. Department of Veterans Affairs, to Transgender American Veterans Association (March 6, 2023)
17.	Letter to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs (March 31, 2023)
18.	Entry RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs (Spring 2023)
19.	Letter from Members of the House of Representatives to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs (March 31, 2023)
20.	Letter from Kimberly M. Mitchell, Director, Veteran Service Organization Liaison, U.S. Department of Veterans Affairs, to Minority Veterans of America (May 2, 2023)

21.	Letters from Honorable Denis McDonough, Secretary, U.S. Department o Veterans Affairs, to Members of Congress (May 9, 2023)	
22.	Entry RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs (Fall 2023)	
23.	Letter from Michael Wishnie, Counsel, Transgender American Veterans Association, to Richard J. Hipolit, Acting General Counsel, U.S. Department of Veterans Affairs (November 20, 2023)	
24.	Letter from Richard J. Hipolit, Acting General Counsel, U.S. Department of Veterans Affairs, to Counsel, Transgender American Veterans Association (December 22, 2023)	
25.	Letter from Michael Wishnie, Counsel, Transgender American Veterans Association, to Richard J. Hipolit Acting General Counsel, U.S. Department of Veterans Affairs, with attachments (January 16, 2024) Appx254	
26.	VHA Directive 1341(3) (May 23, 2018)Appx263	
27.	VHA Directive 2013-003 (January 2017 reissue)Appx289	
28.	Anthony N. Almazan & Alex S. Keuroghlian, "Association Between Gender-Affirming Surgeries and Mental Health Outcomes," 156 J. Am. Med. Ass'n 611 (2021)	
29.	John R. Blosnich et al., "Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care," 103 Am. J. Pub. Health e27 (Oct. 2013)Appx310	
30.	Petition for Review, Fulcher v. Sec'y of Veterans Affs. (No. 2017-1460) (Fed. Cir. June 21, 2017)	
31.	Dismissal Order, Fulcher v. Sec'y of Veterans Affs. (No. 2017-1460) (Fed. Cir. Aug. 1, 2018)	
32.	Leo Shane III, "VA to Offer Gender Surgery to Transgender Veterans for the First Time," Mil. Times (June 19, 2021)Appx323	

<i>33</i> .	Medical Benefits Package," U.S. Department of Veterans Affairs (June 18, 2021
34.	Leo Shane III, "After Two Years, Still No Timeline for Transgender Surgeries at VA," Mil. Times (June 20, 2023)
35.	"Town Hall with VA Secretary Denis McDonough," VA News (Nov. 8, 2023)
36.	Am. Med. Ass' H.D., Resolution 122 (A-08)
37.	William Byne et al., "Report of the APA Task Force on Treatment of Gender Identity Disorder," 169 Am. J. Psychiatry 1 (2012)
38.	Wylie C. Hembree et al., "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," 102 J. Clinical Endocrinology & Metabolism 3869 (2017)
39.	Am. Psychiatric Ass'n, "Gender Dysphoria," in Diagnostic and Statistical Manual of Mental Disorders, Text Revisions 164.0 (5th ed. 2022). Appx417
40.	Declaration of Natalie Rose KastnerAppx429
41.	Declaration of Ray Gibson. Appx433
42.	Declaration of Rebekka EshlerAppx437
43.	Memorandum from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Under Secretary for Health, U.S. Department of Veterans Affairs, "Analysis of Amendment to 38 C.F.R. § 17.38(c)(4) and PACT Act Eligibility" (February 22, 2024)Appx442
44.	DoD Instruction 1300.28 (April 30, 2021)Appx444
45.	Terri Moon Cronk, "DOD Revises Transgender Policies to Align With White House," U.S. Department of Defense (Mar. 31, 2021)Appx466

46.	Steve Beynon, "Army to Provide Gender Transition Care, Surgeries for Transgender Soldiers," Military.com (June 28, 2021)
47.	Cong. Research Serv., "TRICARE Coverage of Gender-Affirming Care," FY2024 NDAA (Jan. 4, 2024)
48.	Mariel Padilla, "Trans Veterans Were Promised Access to Gender-Affirming Surgeries—But It Never Happened," The 19th (January 25, 2024)
49.	Richard Brookshire, "Black Veterans Project Supports Gender-Affirming Care," Black Veterans Project (July 22, 2024)
50.	"Remarks by President Biden at a Veterans Day Wreath Laying Ceremony Arlington, VA," White House (Nov. 11, 2023, 12:00 PM EST) Appx505
51.	U.S. Department of Veterans Affairs, Office of General Counsel, "Regulatory Impact Analysis for RIN 2900-AR57(F), Reproductive Health Services" at 4-5 (Feb. 13, 2024)
52.	"2023 Employer Health Benefits Survey: Section 13: Employer Practices, Telehealth, Provider Networks, Coverage Limits and Coverage for Abortion – Coverage for Gender-Affirming Surgeries," KFF (Oct. 18, 2023)
53.	Press Release, "PACT Act Health Care Expanded Eligibility," U.S. Department of Veterans Affairs (Mar. 6, 2024)
54.	VHA Directive 1091 (February 18, 2020)
55.	U.S. Department of Veterans Affairs, Office of General Counsel, "Regulatory Impact Analysis for RIN 2900-AR57(IF), Reproductive Health Services," (Sept. 1, 2022)
56.	Second Amended Index of Record of Department of Veterans Affairs', February 22, 2024 Denial of Petitioner's Rulemaking Petition Appx570

Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline

Wylie C. Hembree,¹ Peggy T. Cohen-Kettenis,² Louis Gooren,³ Sabine E. Hannema,⁴ Walter J. Meyer,⁵ M. Hassan Murad,⁶ Stephen M. Rosenthal,⁷ Joshua D. Safer,⁸ Vin Tangpricha,⁹ and Guy G. T'Sjoen¹⁰

¹New York Presbyterian Hospital, Columbia University Medical Center, New York, New York 10032 (Retired); ²VU University Medical Center, 1007 MB Amsterdam, Netherlands (Retired); ³VU University Medical Center, 1007 MB Amsterdam, Netherlands (Retired); ⁴Leiden University Medical Center, 2300 RC Leiden, Netherlands; ⁵University of Texas Medical Branch, Galveston, Texas 77555; ⁶Mayo Clinic Evidence-Based Practice Center, Rochester, Minnesota 55905; ⁷University of California San Francisco, Benioff Children's Hospital, San Francisco, California 94143; ⁸Boston University School of Medicine, Boston, Massachusetts 02118; ⁹Emory University School of Medicine and the Atlanta VA Medical Center, Atlanta, Georgia 30322; and ¹⁰Ghent University Hospital, 9000 Ghent, Belgium

*Cosponsoring Associations: American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Pediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society, and World Professional Association for Transgender Health.

Objective: To update the "Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline," published by the Endocrine Society in 2009.

Participants: The participants include an Endocrine Society–appointed task force of nine experts, a methodologist, and a medical writer.

Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation approach to describe the strength of recommendations and the quality of evidence. The task force commissioned two systematic reviews and used the best available evidence from other published systematic reviews and individual studies.

Consensus Process: Group meetings, conference calls, and e-mail communications enabled consensus. Endocrine Society committees, members and cosponsoring organizations reviewed and commented on preliminary drafts of the guidelines.

Conclusion: Gender affirmation is multidisciplinary treatment in which endocrinologists play an important role. Gender-dysphoric/gender-incongruent persons seek and/or are referred to endocrinologists to develop the physical characteristics of the affirmed gender. They require a safe and effective hormone regimen that will (1) suppress endogenous sex hormone secretion determined by the person's genetic/gonadal sex and (2) maintain sex hormone levels within the normal range for the person's affirmed gender. Hormone treatment is not recommended for prepubertal gender-dysphoric/gender-incongruent persons. Those clinicians who recommend gender-affirming endocrine treatments—appropriately trained diagnosing clinicians (required), a mental health provider for adolescents (required) and mental health

ISSN Print 0021-972X ISSN Online 1945-7197 Printed in USA Copyright © 2017 Endocrine Society Received 24 July 2017. Accepted 24 August 2017. First Published Online 13 September 2017

doi: 10.1210/jc.2017-01658

Abbreviations: BMD, bone mineral density; DSD, disorder/difference of sex development; DSM, Diagnostic and Statistical Manual of Mental Disorders; GD, gender dysphoria; GnRH, gonadotropin-releasing hormone; ICD, International Statistical Classification of Diseases and Related Health Problems; MHP, mental health professional; VTE, venous thromboembolism.

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

professional for adults (recommended)—should be knowledgeable about the diagnostic criteria and criteria for gender-affirming treatment, have sufficient training and experience in assessing psychopathology, and be willing to participate in the ongoing care throughout the endocrine transition. We recommend treating gender-dysphoric/gender-incongruent adolescents who have entered puberty at Tanner Stage G2/B2 by suppression with gonadotropin-releasing hormone agonists. Clinicians may add gender-affirming hormones after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent to this partially irreversible treatment. Most adolescents have this capacity by age 16 years old. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to age 16 years, although there is minimal published experience treating prior to 13.5 to 14 years of age. For the care of peripubertal youths and older adolescents, we recommend that an expert multidisciplinary team comprised of medical professionals and mental health professionals manage this treatment. The treating physician must confirm the criteria for treatment used by the referring mental health practitioner and collaborate with them in decisions about gender-affirming surgery in older adolescents. For adult gender-dysphoric/gender-incongruent persons, the treating clinicians (collectively) should have expertise in transgender-specific diagnostic criteria, mental health, primary care, hormone treatment, and surgery, as needed by the patient. We suggest maintaining physiologic levels of gender-appropriate hormones and monitoring for known risks and complications. When high doses of sex steroids are required to suppress endogenous sex steroids and/or in advanced age, clinicians may consider surgically removing natal gonads along with reducing sex steroid treatment. Clinicians should monitor both transgender males (female to male) and transgender females (male to female) for reproductive organ cancer risk when surgical removal is incomplete. Additionally, clinicians should persistently monitor adverse effects of sex steroids. For gender-affirming surgeries in adults, the treating physician must collaborate with and confirm the criteria for treatment used by the referring physician. Clinicians should avoid harming individuals (via hormone treatment) who have conditions other than gender dysphoria/gender incongruence and who may not benefit from the physical changes associated with this treatment. U Clin Endocrinol Metab 102: 3869-3903, 2017)

Summary of Recommendations

1.0 Evaluation of youth and adults

- 1.1. We advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/ gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/ gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)
- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).

AR1049 Appx383 doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem 3871

1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. $(1 \mid \oplus \oplus \oplus \bigcirc)$

2.0 Treatment of adolescents

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 l⊕⊕○○)
- 2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. $(2 \mid \oplus \oplus \bigcirc)$
- 2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$
- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. $(1 \mid \oplus \oplus \bigcirc)$.
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/ gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 $|\oplus \bigcirc \bigcirc \bigcirc$)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment. $(2 \mid \oplus \oplus \bigcirc\bigcirc)$

3.0 Hormonal therapy for transgender adults

3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and AR1050

- the criteria for the endocrine phase of gender transition before beginning treatment. $(1 \mid \oplus \oplus \oplus \bigcirc)$
- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. $(1 \mid \oplus \oplus \oplus \bigcirc)$
- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. $(2 \mid \oplus \oplus \bigcirc)$
- 3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. $(2 \mid \oplus \bigcirc \bigcirc \bigcirc)$

4.0 Adverse outcome prevention and long-term care

- 4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 $\mid \oplus \oplus \bigcirc \bigcirc$)
- 4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$
- 4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 1⊕⊕○○)
- 4.4. We recommend that clinicians obtain bone mineral density (BMD) measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. $(1 \mid \oplus \oplus \bigcirc\bigcirc)$
- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for non-transgender females. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 l⊕○○○)
- 4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

5.0 Surgery for sex reassignment and gender confirmation

5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 |⊕⊕○○)

Case: 24-1714

Case: 24-108

- 5.2. We advise that clinicians approve genital genderaffirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 □○○○)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 l⊕⊕○○).
- 5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 |⊕○○○)

Changes Since the Previous Guideline

Both the current guideline and the one published in 2009 contain similar sections. Listed here are the sections contained in the current guideline and the corresponding number of recommendations: Introduction, Evaluation of Youth and Adults (5), Treatment of Adolescents (6), Hormonal Therapy for Transgender Adults (4), Adverse Outcomes Prevention and Long-term Care (7), and Surgery for Sex Reassignment and Gender Confirmation (6). The current introduction updates the diagnostic classification of "gender dysphoria/gender incongruence." It also reviews the development of "gender identity" and summarizes its natural development. The section on

clinical evaluation of both youth and adults, defines in detail the professional qualifications required of those who diagnose and treat both adolescents and adults. We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional. We recommend against puberty blocking followed by gender-affirming hormone treatment of prepubertal children. Clinicians should inform pubertal children, adolescents, and adults seeking genderconfirming treatment of their options for fertility preservation. Prior to treatment, clinicians should evaluate the presence of medical conditions that may be worsened by hormone depletion and/or treatment. A multidisciplinary team, preferably composed of medical and mental health professionals, should monitor treatments. Clinicians evaluating transgender adults for endocrine treatment should confirm the diagnosis of persistent gender dysphoria/gender incongruence. Physicians should educate transgender persons regarding the time course of steroid-induced physical changes. Treatment should include periodic monitoring of hormone levels and metabolic parameters, as well as assessments of bone density and the impact upon prostate, gonads, and uterus. We also make recommendations for transgender persons who plan genital gender-affirming surgery.

Method of Development of Evidence-Based Clinical Practice Guidelines

The Clinical Guidelines Subcommittee (CGS) of the Endocrine Society deemed the diagnosis and treatment of individuals with GD/gender incongruence a priority area for revision and appointed a task force to formulate evidence-based recommendations. The task force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation group, an international group with expertise in the development and implementation of evidence-based guidelines (1). A detailed description of the grading scheme has been published elsewhere (2). The task force used the best available research evidence to develop the recommendations. The task force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase "we recommend" and the number 1, and weak recommendations use the phrase "we suggest" and the number 2. Cross-filled circles indicate the quality of the evidence, such that $\oplus \bigcirc \bigcirc \bigcirc$ denotes very low-quality evidence; $\oplus \oplus \bigcirc \bigcirc$, low quality; $\oplus \oplus \ominus \bigcirc$, moderate quality; and $\oplus \ominus \ominus \ominus \bigcirc$, high quality. The task force has confidence that persons who receive care according to the strong recommendations will derive, on average, more benefit than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each recommendation is a description of the evidence and the Case: 24-1714 Document: 78-2 Page: 11 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 86 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3873**

values that the task force considered in making the recommendation. In some instances, there are remarks in which the task force offers technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the task force and their preferences; therefore, one should consider these remarks as suggestions.

In this guideline, the task force made several statements to emphasize the importance of shared decision-making, general preventive care measures, and basic principles of the treatment of transgender persons. They labeled these "Ungraded Good Practice Statement." Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles.

The Endocrine Society maintains a rigorous conflict-of-interest review process for developing clinical practice guidelines. All task force members must declare any potential conflicts of interest by completing a conflict-of-interest form. The CGS reviews all conflicts of interest before the Society's Council approves the members to participate on the task force and periodically during the development of the guideline. All others participating in the guideline's development must also disclose any conflicts of interest in the matter under study, and most of these participants must be without any conflicts of interest. The CGS and the task force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined as remuneration in any amount from commercial interests; grants; research support; consulting fees; salary; ownership interests [e.g., stocks and stock options (excluding diversified mutual funds)]; honoraria and other payments for participation in speakers' bureaus, advisory boards, or boards of directors; and all other financial benefits. Completed forms are available through the Endocrine Society office.

The Endocrine Society provided the funding for this guideline; the task force received no funding or remuneration from commercial or other entities.

Commissioned Systematic Review

The task force commissioned two systematic reviews to support this guideline. The first one aimed to summarize the available evidence on the effect of sex steroid use in transgender individuals on lipids and cardiovascular outcomes. The review identified 29 eligible studies at moderate risk of bias. In transgender males (female to male), sex steroid therapy was associated with a statistically significant increase in serum triglycerides and low-density lipoprotein cholesterol levels. High-density lipoprotein cholesterol levels decreased significantly across all follow-up time periods. In transgender females (male to female), serum triglycerides were significantly higher without any changes in other parameters. Few myocardial infarction, stroke, venous thromboembolism (VTE), and death events were reported. These events were more frequent in transgender females. However, the quality of the evidence was low. The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals and identified 13 studies. In transgender males, there was no statistically significant difference in the lumbar spine, femoral neck, or total hip BMD at 12 and 24 months compared with baseline values before initiating masculinizing hormone therapy. In transgender females, there was a statistically significant increase in lumbar spine BMD at 12 months and 24 months compared with baseline values before initiation of feminizing hormone therapy. There was minimal information on fracture rates. The quality of evidence was also low.

Introduction

Throughout recorded history (in the absence of an endocrine disorder) some men and women have experienced confusion and anguish resulting from rigid, forced conformity to sexual dimorphism. In modern history, there have been numerous ongoing biological, psychological, cultural, political, and sociological debates over various aspects of gender variance. The 20th century marked the emergence of a social awakening for men and women with the belief that they are "trapped" in the wrong body (3). Magnus Hirschfeld and Harry Benjamin, among others, pioneered the medical responses to those who sought relief from and a resolution to their profound discomfort. Although the term transsexual became widely known after Benjamin wrote "The Transsexual Phenomenon" (4), it was Hirschfeld who coined the term "transsexual" in 1923 to describe people who want to live a life that corresponds with their experienced gender vs their designated gender (5). Magnus Hirschfeld (6) and others (4, 7) have described other types of trans phenomena besides transsexualism. These early researchers proposed that the gender identity of these people was located somewhere along a unidimensional continuum. This continuum ranged from all male through "something in between" to all female. Yet such a classification does not take into account that people may have gender identities outside this continuum. For instance, some experience themselves as having both a male and female gender identity, whereas others completely renounce any gender classification (8, 9). There are also reports of individuals experiencing a continuous and rapid involuntary alternation between a male and female identity (10) or men who do not experience themselves as men but do not want to live as women (11, 12). In some countries, (e.g., Nepal, Bangladesh, and Australia), these nonmale or nonfemale genders are officially recognized (13). Specific treatment protocols, however, have not yet been developed for these groups.

studies across countries that use the same diagnostic and inclusion criteria, medications, assay methods, and response assessment tools (e.g., the European Network for the Investigation of Gender Incongruence) (17, 18).

Terminology and its use vary and continue to evolve. Table 1 contains the definitions of terms as they are used throughout this guideline.

Instead of the term transsexualism, the current classification system of the American Psychiatric Association uses the term gender dysphoria in its diagnosis of persons who are not satisfied with their designated gender (14). The current version of the World Health Organization's ICD-10 still uses the term transsexualism when diagnosing adolescents and adults. However, for the ICD-11, the World Health Organization has proposed using the term "gender incongruence" (15).

Case: 24-1714

Case: 24-108

Treating persons with GD/gender incongruence (15) was previously limited to relatively ineffective elixirs or creams. However, more effective endocrinology-based treatments became possible with the availability of testosterone in 1935 and diethylstilbestrol in 1938. Reports of individuals with GD/gender incongruence who were treated with hormones and gender-affirming surgery appeared in the press during the second half of the 20th century. The Harry Benjamin International Gender Dysphoria Association was founded in September 1979 and is now called the World Professional Association for Transgender Health (WPATH). WPATH published its first Standards of Care in 1979. These standards have since been regularly updated, providing guidance for treating persons with GD/gender incongruence (16).

Prior to 1975, few peer-reviewed articles were published concerning endocrine treatment of transgender persons. Since then, more than two thousand articles about various aspects of transgender care have appeared.

It is the purpose of this guideline to make detailed recommendations and suggestions, based on existing medical literature and clinical experience, that will enable treating physicians to maximize benefit and minimize risk when caring for individuals diagnosed with GD/gender incongruence.

In the future, we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols. Specifically, endocrine treatment protocols for GD/gender incongruence should include the careful assessment of the following: (1) the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development); (2) the effects of treatment in adults on sex hormone levels; (3) the requirement for and the effects of progestins and other agents used to suppress endogenous sex steroids during treatment; and (4) the risks and benefits of gender-affirming hormone treatment in older transgender people.

To successfully establish and enact these protocols, a commitment of mental health and endocrine investigators is required to collaborate in long-term, large-scale

Biological Determinants of Gender Identity Development

One's self-awareness as male or female changes gradually during infant life and childhood. This process of cognitive and affective learning evolves with interactions with parents, peers, and environment. A fairly accurate timetable exists outlining the steps in this process (19). Normative psychological literature, however, does not address if and when gender identity becomes crystallized and what factors contribute to the development of a gender identity that is not congruent with the gender of rearing. Results of studies from a variety of biomedical disciplines—genetic, endocrine, and neuroanatomic—support the concept that gender identity and/or gender expression (20) likely reflect a complex interplay of biological, environmental, and cultural factors (21, 22).

With respect to endocrine considerations, studies have failed to find differences in circulating levels of sex steroids between transgender and nontransgender individuals (23). However, studies in individuals with a disorder/difference of sex development (DSD) have informed our understanding of the role that hormones may play in gender identity outcome, even though most persons with GD/gender incongruence do not have a DSD. For example, although most 46,XX adult individuals with virilizing congenital adrenal hyperplasia caused by mutations in CYP21A2 reported a female gender identity, the prevalence of GD/gender incongruence was much greater in this group than in the general population without a DSD. This supports the concept that there is a role for prenatal/postnatal androgens in gender development (24–26), although some studies indicate that prenatal androgens are more likely to affect gender behavior and sexual orientation rather than gender identity per se (27, 28).

Researchers have made similar observations regarding the potential role of androgens in the development of gender identity in other individuals with DSD. For example, a review of two groups of 46,XY persons, each with androgen synthesis deficiencies and female raised, reported transgender male (female-to-male) gender role changes in 56% to 63% and 39% to 64% of patients, respectively (29). Also, in 46,XY female-raised individuals with cloacal

Case: 24-1714 Document: 78-2 Page: 13 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 88 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3875**

Table 1. Definitions of Terms Used in This Guideline

Biological sex, biological male or female: These terms refer to physical aspects of maleness and femaleness. As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided.

Cisgender: This means not transgender. An alternative way to describe individuals who are not transgender is "non-transgender people."

Gender-affirming (hormone) treatment: See "gender reassignment"

Gender dysphoria: This is the distress and unease experienced if gender identity and designated gender are not completely congruent (see Table 2). In 2013, the American Psychiatric Association released the fifth edition of the DSM-5, which replaced "gender identity disorder" with "gender dysphoria" and changed the criteria for diagnosis.

Gender expression: This refers to external manifestations of gender, expressed through one's name, pronouns, clothing, haircut, behavior, voice, or body characteristics. Typically, transgender people seek to make their gender expression align with their gender identity, rather than their designated gender.

Gender identity/experienced gender: This refers to one's internal, deeply held sense of gender. For transgender people, their gender identity does not match their sex designated at birth. Most people have a gender identity of man or woman (or boy or girl). For some people, their gender identity does not fit neatly into one of those two choices. Unlike gender expression (see below), gender identity is not visible to others.

Gender identity disorder: This is the term used for GD/gender incongruence in previous versions of DSM (see "gender dysphoria"). The ICD-10 still uses the term for diagnosing child diagnoses, but the upcoming ICD-11 has proposed using "gender incongruence of childhood."

Gender incongruence: This is an umbrella term used when the gender identity and/or gender expression differs from what is typically associated with the designated gender. Gender incongruence is also the proposed name of the gender identity–related diagnoses in ICD-11. Not all individuals with gender incongruence have gender dysphoria or seek treatment.

Gender variance: See "gender incongruence"

Gender reassignment: This refers to the treatment procedure for those who want to adapt their bodies to the experienced gender by means of hormones and/or surgery. This is also called gender-confirming or gender-affirming treatment.

Gender-reassignment surgery (gender-confirming/gender-affirming surgery): These terms refer only to the surgical part of gender-confirming/gender-affirming treatment.

Gender role: This refers to behaviors, attitudes, and personality traits that a society (in a given culture and historical period) designates as masculine or feminine and/or that society associates with or considers typical of the social role of men or women.

Sex designated at birth: This refers to sex assigned at birth, usually based on genital anatomy.

Sex: This refers to attributes that characterize biological maleness or femaleness. The best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, the gonads, sex hormones, internal and external genitalia, and secondary sex characteristics.

Sexual orientation: This term describes an individual's enduring physical and emotional attraction to another person. Gender identity and sexual orientation are not the same. Irrespective of their gender identity, transgender people may be attracted to women (gynephilic), attracted to men (androphilic), bisexual, asexual, or queer.

Transgender: This is an umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with their sex designated at birth. Not all transgender individuals seek treatment.

Transgender male (also: trans man, female-to-male, transgender male): This refers to individuals assigned female at birth but who identify and live as men.

Transgender woman (also: trans woman, male-to female, transgender female): This refers to individuals assigned male at birth but who identify and live as women.

Transition: This refers to the process during which transgender persons change their physical, social, and/or legal characteristics consistent with the affirmed gender identity. Prepubertal children may choose to transition socially.

Transsexual: This is an older term that originated in the medical and psychological communities to refer to individuals who have permanently transitioned through medical interventions or desired to do so.

exstrophy and penile agenesis, the occurrence of transgender male changes was significantly more prevalent than in the general population (30, 31). However, the fact that a high percentage of individuals with the same conditions did not change gender suggests that cultural factors may play a role as well.

With respect to genetics and gender identity, several studies have suggested heritability of GD/gender incongruence (32, 33). In particular, a study by Heylens *et al.* (33) demonstrated a 39.1% concordance rate for gender identity disorder (based on the DSM-IV criteria) in 23 monozygotic twin pairs but no concordance in 21 same-sex dizygotic or seven opposite-sex twin pairs. Although numerous investigators have sought to identify

specific genes associated with GD/gender incongruence, such studies have been inconsistent and without strong statistical significance (34–38).

Studies focusing on brain structure suggest that the brain phenotypes of people with GD/gender incongruence differ in various ways from control males and females, but that there is not a complete sex reversal in brain structures (39).

In summary, although there is much that is still unknown with respect to gender identity and its expression, compelling studies support the concept that biologic factors, in addition to environmental factors, contribute to this fundamental aspect of human development.

Natural History of Children With GD/Gender Incongruence

With current knowledge, we cannot predict the psychosexual outcome for any specific child. Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called "desisters"). Combining all outcome studies to date, the GD/gender incongruence of a minority of prepubertal children appears to persist in adolescence (20, 40). In adolescence, a significant number of these desisters identify as homosexual or bisexual. It may be that children who only showed some gender nonconforming characteristics have been included in the follow-up studies, because the DSM-IV text revision criteria for a diagnosis were rather broad. However, the persistence of GD/gender incongruence into adolescence is more likely if it had been extreme in childhood (41, 42). With the newer, stricter criteria of the DSM-5 (Table 2), persistence rates may well be different in future studies.

1.0 Evaluation of Youth and Adults

Gender-affirming treatment is a multidisciplinary effort. After evaluation, education, and diagnosis, treatment may include mental health care, hormone therapy, and/or surgical therapy. Together with an MHP, hormone-prescribing clinicians should examine the psychosocial impact of the potential changes on people's lives, including mental health, friends, family, jobs, and their role in society. Transgender individuals should be encouraged to experience living in the new gender role and assess whether

this improves their quality of life. Although the focus of this guideline is gender-affirming hormone therapy, collaboration with appropriate professionals responsible for each aspect of treatment maximizes a successful outcome.

Diagnostic assessment and mental health care

GD/gender incongruence may be accompanied with psychological or psychiatric problems (43-51). It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient's understanding, mental health, and social conditions that can impact genderaffirming hormone therapy, and (6) regularly attend relevant professional meetings.

Because of the psychological vulnerability of many individuals with GD/gender incongruence, it is important that mental health care is available before, during, and sometimes also after transitioning. For children and adolescents, an MHP who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing GD/gender incongruence in children and adolescents is often extremely complex.

During assessment, the clinician obtains information from the individual seeking gender-affirming treatment. In the case

Table 2. DSM-5 Criteria for Gender Dysphoria in Adolescents and Adults

- A. A marked incongruence between one's experienced/expressed gender and natal gender of at least 6 mo in duration, as manifested by at least two of the following:
 - 1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
 - 2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
 - 3. A strong desire for the primary and/or secondary sex characteristics of the other gender
 - 4. A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
 - 5. A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
 - 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender)
- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- Specify if:
 - 1. The condition exists with a disorder of sex development.
 - 2. The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

Case: 24-1714 Document: 78-2 Page: 15 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 90 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3877**

of adolescents, the clinician also obtains information from the parents or guardians regarding various aspects of the child's general and psychosexual development and current functioning. On the basis of this information, the clinician:

- decides whether the individual fulfills criteria for treatment (see Tables 2 and 3) for GD/gender incongruence (DSM-5) or transsexualism (DSM-5 and/or ICD-10);
- informs the individual about the possibilities and limitations of various kinds of treatment (hormonal/ surgical and nonhormonal), and if medical treatment is desired, provides correct information to prevent unrealistically high expectations;
- assesses whether medical interventions may result in unfavorable psychological and social outcomes.

In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues. Literature on postoperative regret suggests that besides poor quality of surgery, severe psychiatric comorbidity and lack of support may interfere with positive outcomes (52–56).

For adolescents, the diagnostic procedure usually includes a complete psychodiagnostic assessment (57) and an assessment of the decision-making capability of the youth. An evaluation to assess the family's ability to endure stress, give support, and deal with the complexities of the adolescent's situation should be part of the diagnostic phase (58).

Social transitioning

A change in gender expression and role (which may involve living part time or full time in another gender role that is consistent with one's gender identity) may test the person's resolve, the capacity to function in the affirmed gender, and the adequacy of social, economic, and psychological supports. It assists both the individual and the clinician in their judgments about how to proceed (16). During social transitioning, the person's feelings about the social transformation (including coping with the responses of others) is a major focus of the counseling. The optimal timing for social transitioning may differ between individuals. Sometimes people wait until they

start gender-affirming hormone treatment to make social transitioning easier, but individuals increasingly start social transitioning long before they receive medically supervised, gender-affirming hormone treatment.

Criteria

Adolescents and adults seeking gender-affirming hormone treatment and surgery should satisfy certain criteria before proceeding (16). Criteria for gender-affirming hormone therapy for adults are in Table 4, and criteria for gender-affirming hormone therapy for adolescents are in Table 5. Follow-up studies in adults meeting these criteria indicate a high satisfaction rate with treatment (59). However, the quality of evidence is usually low. A few follow-up studies on adolescents who fulfilled these criteria also indicated good treatment results (60–63).

Recommendations for Those Involved in the Gender-Affirming Hormone Treatment of Individuals With GD/Gender Incongruence

- 1.1. We advise that only trained MHPs who meet the following criteria should diagnose GD/gender incongruence in adults: (1) competence in using the DSM and/or the ICD for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or ICD for diagnostic

Table 3. ICD-10 Criteria for Transsexualism

Transsexualism (F64.0) has three criteria:

- 1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
- 2. The transsexual identity has been present persistently for at least 2 y.
- 3. The disorder is not a symptom of another mental disorder or a genetic, DSD, or chromosomal abnormality.

Table 4. Criteria for Gender-Affirming Hormone Therapy for Adults

- 1. Persistent, well-documented gender dysphoria/gender incongruence
- 2. The capacity to make a fully informed decision and to consent for treatment
- 3. The age of majority in a given country (if younger, follow the criteria for adolescents)
- 4. Mental health concerns, if present, must be reasonably well controlled

Reproduced from World Professional Association for Transgender Health (16).

purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

Evidence

Individuals with gender identity issues may have psychological or psychiatric problems (43-48, 50, 51, 64, 65). It is therefore necessary that clinicians making the diagnosis are able to make a distinction between GD/ gender incongruence and conditions that have similar features. Examples of conditions with similar features are body dysmorphic disorder, body identity integrity disorder (a condition in which individuals have a sense that their anatomical configuration as an able-bodied person is somehow wrong or inappropriate) (66), or certain forms of eunuchism (in which a person is preoccupied with or engages in castration and/or penectomy for

Table 5. Criteria for Gender-Affirming Hormone Therapy for Adolescents

Adolescents are eligible for GnRH agonist treatment if:

- 1. A qualified MHP has confirmed that:
- •the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed),
- •gender dysphoria worsened with the onset of puberty,
- •any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
- •the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment,
- 2. And the adolescent:
- has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or quardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
- 3. And a pediatric endocrinologist or other clinician experienced in pubertal assessment
- •agrees with the indication for GnRH agonist treatment,
- has confirmed that puberty has started in the adolescent (Tanner stage ≥G2/B2),
- has confirmed that there are no medical contraindications to GnRH agonist treatment.

Adolescents are eligible for subsequent sex hormone treatment if:

- 1. A qualified MHP has confirmed:
- •the persistence of gender dysphoria,
- any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone
- •the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
- 2. And the adolescent:
- has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or quardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
- 3. And a pediatric endocrinologist or other clinician experienced in pubertal induction:
- agrees with the indication for sex hormone treatment,
- has confirmed that there are no medical contraindications to sex hormone treatment.

Case: 24-1714 Document: 78-2 Page: 17 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 92 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3879**

reasons that are not gender identity related) (11). Clinicians should also be able to diagnose psychiatric conditions accurately and ensure that these conditions are treated appropriately, particularly when the conditions may complicate treatment, affect the outcome of genderaffirming treatment, or be affected by hormone use.

Values and preferences

The task force placed a very high value on avoiding harm from hormone treatment in individuals who have conditions other than GD/gender incongruence and who may not benefit from the physical changes associated with this treatment and placed a low value on any potential benefit these persons believe they may derive from hormone treatment. This justifies the good practice statement.

- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).
- 1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. (1 l⊕⊕○○)

Evidence

In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. The percentages differed among studies, probably dependent on which version of the DSM clinicians used, the patient's age, the recruitment criteria, and perhaps cultural factors. However, the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/ gender incongruent in adolescence (20). If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty (40). Social transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence. It may be that the presence of GD/gender incongruence in prepubertal children is the earliest sign that a child is destined to be transgender as an adolescent/adult (20). However, social transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence.

This recommendation, however, does not imply that children should be discouraged from showing gender-variant behaviors or should be punished for exhibiting such behaviors. In individual cases, an early complete social transition may result in a more favorable outcome, but there are currently no criteria to identify the

GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty.

Values and preferences

The task force placed a high value on avoiding harm with gender-affirming hormone therapy in prepubertal children with GD/gender incongruence. This justifies the strong recommendation in the face of low-quality evidence.

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 l⊕⊕⊕○)

Remarks

Persons considering hormone use for gender affirmation need adequate information about this treatment in general and about fertility effects of hormone treatment in particular to make an informed and balanced decision (67, 68). Because young adolescents may not feel qualified to make decisions about fertility and may not fully understand the potential effects of hormonal interventions, consent and protocol education should include parents, the referring MHP(s), and other members of the adolescent's support group. To our knowledge, there are no formally evaluated decision aids available to assist in the discussion and decision regarding the future fertility of adolescents or adults beginning gender-affirming treatment.

Treating early pubertal youth with GnRH analogs will temporarily impair spermatogenesis and oocyte maturation. Given that an increasing number of transgender youth want to preserve fertility potential, delaying or temporarily discontinuing GnRH analogs to promote gamete maturation is an option. This option is often not preferred, because mature sperm production is associated with later stages of puberty and with the significant development of secondary sex characteristics.

For those designated male at birth with GD/gender incongruence and who are in early puberty, sperm production and the development of the reproductive tract are insufficient for the cryopreservation of sperm. However, prolonged pubertal suppression using GnRH analogs is reversible and clinicians should inform these individuals that sperm production can be initiated following prolonged gonadotropin suppression. This can be accomplished by spontaneous gonadotropin recovery after

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

cessation of GnRH analogs or by gonadotropin treatment and will probably be associated with physical manifestations of testosterone production, as stated above. Note that there are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility. In males treated for precocious puberty, spermarche was reported 0.7 to 3 years after cessation of GnRH analogs (69). In adult men with gonadotropin deficiency, sperm are noted in seminal fluid by 6 to 12 months of gonadotropin treatment. However, sperm numbers when partners of these patients conceive are far below the "normal range" (70, 71).

Case: 24-1714

Case: 24-108

In girls, no studies have reported long-term, adverse effects of pubertal suppression on ovarian function after treatment cessation (72, 73). Clinicians should inform adolescents that no data are available regarding either time to spontaneous ovulation after cessation of GnRH analogs or the response to ovulation induction following prolonged gonadotropin suppression.

In males with GD/gender incongruence, when medical treatment is started in a later phase of puberty or in adulthood, spermatogenesis is sufficient for cryopreservation and storage of sperm. In vitro spermatogenesis is currently under investigation. Restoration of spermatogenesis after prolonged estrogen treatment has not been studied.

In females with GD/gender incongruence, the effect of prolonged treatment with exogenous testosterone on ovarian function is uncertain. There have been reports of an increased incidence of polycystic ovaries in transgender males, both prior to and as a result of androgen treatment (74–77), although these reports were not confirmed by others (78). Pregnancy has been reported in transgender males who have had prolonged androgen treatment and have discontinued testosterone but have not had genital surgery (79, 80). A reproductive endocrine gynecologist can counsel patients before genderaffirming hormone treatment or surgery regarding potential fertility options (81). Techniques for cryopreservation of oocytes, embryos, and ovarian tissue continue to improve, and oocyte maturation of immature tissue is being studied (82).

2.0 Treatment of Adolescents

During the past decade, clinicians have progressively acknowledged the suffering of young adolescents with GD/gender incongruence. In some forms of GD/gender incongruence, psychological interventions may be useful and sufficient. However, for many adolescents with GD/ gender incongruence, the pubertal physical changes are unbearable. As early medical intervention may prevent psychological harm, various clinics have decided to start treating young adolescents with GD/gender incongruence with puberty-suppressing medication (a GnRH analog). As compared with starting gender-affirming treatment long after the first phases of puberty, a benefit of pubertal suppression at early puberty may be a better psychological and physical outcome.

In girls, the first physical sign of puberty is the budding of the breasts followed by an increase in breast and fat tissue. Breast development is also associated with the pubertal growth spurt, and menarche occurs ~2 years later. In boys, the first physical change is testicular growth. A testicular volume ≥4 mL is seen as consistent with the initiation of physical puberty. At the beginning of puberty, estradiol and testosterone levels are still low and are best measured in the early morning with an ultrasensitive assay. From a testicular volume of 10 mL, daytime testosterone levels increase, leading to virilization (83). Note that pubic hair and/or axillary hair/odor may not reflect the onset of gonadarche; instead, it may reflect adrenarche alone.

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment (Table 5), and are requesting treatment should initially undergo treatment to suppress pubertal development. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$
- 2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty (Tanner stages G2/B2). (2 I⊕⊕○○)

Evidence

Pubertal suppression can expand the diagnostic phase by a long period, giving the subject more time to explore options and to live in the experienced gender before making a decision to proceed with gender-affirming sex hormone treatments and/or surgery, some of which is irreversible (84, 85). Pubertal suppression is fully reversible, enabling full pubertal development in the natal gender, after cessation of treatment, if appropriate. The experience of full endogenous puberty is an undesirable condition for the GD/gender-incongruent individual and may seriously interfere with healthy psychological functioning and well-being. Treating GD/gender-incongruent adolescents entering puberty with GnRH analogs has been shown to improve psychological functioning in several domains (86).

Another reason to start blocking pubertal hormones early in puberty is that the physical outcome is improved compared with initiating physical transition after puberty has been completed (60, 62). Looking like a man or woman when living as the opposite sex creates difficult

Downloaded from https://academic.oup.com/jcem/article/102/11/3869/4157558 by Yale University, Cushing/Whitney Medical Library user on 04 December 2023

barriers with enormous life-long disadvantages. We therefore advise starting suppression in early puberty to prevent the irreversible development of undesirable secondary sex characteristics. However, adolescents with GD/gender incongruence should experience the first changes of their endogenous spontaneous puberty, because their emotional reaction to these first physical changes has diagnostic value in establishing the persistence of GD/gender incongruence (85). Thus, Tanner stage 2 is the optimal time to start pubertal suppression. However, pubertal suppression treatment in early puberty will limit the growth of the penis and scrotum, which will have a potential effect on future surgical treatments (87).

Clinicians can also use pubertal suppression in adolescents in later pubertal stages to stop menses in transgender males and prevent facial hair growth in transgender females. However, in contrast to the effects in early pubertal adolescents, physical sex characteristics (such as more advanced breast development in transgender boys and lowering of the voice and outgrowth of the jaw and brow in transgender girls) are not reversible.

Values and preferences

These recommendations place a high value on avoiding an unsatisfactory physical outcome when secondary sex characteristics have become manifest and irreversible, a higher value on psychological well-being, and a lower value on avoiding potential harm from early pubertal suppression.

Remarks

Table 6 lists the Tanner stages of breast and male genital development. Careful documentation of hallmarks of pubertal development will ensure precise timing when initiating pubertal suppression once puberty has started. Clinicians can use pubertal LH and sex steroid levels to confirm that puberty has progressed sufficiently before starting pubertal suppression (88). Reference ranges for sex steroids by Tanner stage may vary depending on the assay used. Ultrasensitive sex steroid and gonadotropin assays will help clinicians document early pubertal changes.

Irreversible and, for GD/gender-incongruent adolescents, undesirable sex characteristics in female puberty are breasts, female body habitus, and, in some cases, relative short stature. In male puberty, they are a prominent Adam's apple; low voice; male bone configuration, such as a large jaw, big feet and hands, and tall stature; and male hair pattern on the face and extremities.

2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$

Evidence

Clinicians can suppress pubertal development and gonadal function most effectively via gonadotropin suppression using GnRH analogs. GnRH analogs are long-acting agonists that suppress gonadotropins by GnRH receptor desensitization after an initial increase of gonadotropins during ~ 10 days after the first and (to a lesser degree) the second injection (89). Antagonists immediately suppress pituitary gonadotropin secretion (90, 91). Long-acting GnRH analogs are the currently preferred treatment option. Clinicians may consider longacting GnRH antagonists when evidence on their safety and efficacy in adolescents becomes available.

During GnRH analog treatment, slight development of secondary sex characteristics may regress, and in a later phase of pubertal development, it will stop. In girls, breast tissue will become atrophic, and menses will stop. In boys, virilization will stop, and testicular volume may decrease (92).

An advantage of using GnRH analogs is the reversibility of the intervention. If, after extensive exploration of his/her transition wish, the individual no longer desires transition, they can discontinue pubertal suppression. In subjects with

Table 6. Tanner Stages of Breast Development and Male External Genitalia

The description of Tanner stages for breast development:

- 1. Prepubertal
- 2. Breast and papilla elevated as small mound; areolar diameter increased
- 3. Breast and areola enlarged, no contour separation
- 4. Areola and papilla form secondary mound
- 5. Mature; nipple projects, areola part of general breast contour For penis and testes:
 - 1. Prepubertal, testicular volume <4 mL
 - 2. Slight enlargement of penis; enlarged scrotum, pink, texture altered, testes 4–6 mL
 - 3. Penis longer, testes larger (8–12 mL)
 - 4. Penis and glans larger, including increase in breadth; testes larger (12–15 mL), scrotum dark
 - 5. Penis adult size; testicular volume > 15 ml

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

precocious puberty, spontaneous pubertal development has been shown to resume after patients discontinue taking GnRH analogs (93).

Recommendations 2.1 to 2.3 are supported by a prospective follow-up study from The Netherlands. This report assessed mental health outcomes in 55 transgender adolescents/young adults (22 transgender females and 33 transgender males) at three time points: (1) before the start of GnRH agonist (average age of 14.8 years at start of treatment), (2) at initiation of gender-affirming hormones (average age of 16.7 years at start of treatment), and (3) 1 year after "gender-reassignment surgery" (average age of 20.7 years) (63). Despite a decrease in depression and an improvement in general mental health functioning, GD/gender incongruence persisted through pubertal suppression, as previously reported (86). However, following sex hormone treatment and genderreassignment surgery, GD/gender incongruence was resolved and psychological functioning steadily improved (63). Furthermore, well-being was similar to or better than that reported by age-matched young adults from the general population, and none of the study participants regretted treatment. This study represents the first longterm follow-up of individuals managed according to currently existing clinical practice guidelines for transgender youth, and it underscores the benefit of the multidisciplinary approach pioneered in The Netherlands; however, further studies are needed.

Side effects

The primary risks of pubertal suppression in GD/ gender-incongruent adolescents may include adverse effects on bone mineralization (which can theoretically be reversed with sex hormone treatment), compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development. Few data are available on the effect of GnRH analogs on BMD in adolescents with GD/gender incongruence. Initial data in GD/gender-incongruent subjects demonstrated no change of absolute areal BMD during 2 years of GnRH analog therapy but a decrease in BMD z scores (85). A recent study also suggested suboptimal bone mineral accrual during GnRH analog treatment. The study reported a decrease in areal BMD z scores and of bone mineral apparent density z scores (which takes the size of the bone into account) in 19 transgender males treated with GnRH analogs from a mean age of 15.0 years (standard deviation = 2.0 years) for a median duration of 1.5 years (0.3 to 5.2 years) and in 15 transgender females treated from 14.9 (± 1.9) years for 1.3 years (0.5) to 3.8 years), although not all changes were statistically significant (94). There was incomplete catch-up at age 22 years after sex hormone treatment from age 16.6 (\pm 1.4) years for a median duration of 5.8 years (3.0 to 8.0 years) in transgender females and from age $16.4 (\pm 2.3)$ years for 5.4 years (2.8 to 7.8 years) in transgender males. Little is known about more prolonged use of GnRH analogs. Researchers reported normal BMD z scores at age 35 years in one individual who used GnRH analogs from age 13.7 years until age 18.6 years before initiating sex hormone treatment (65).

Additional data are available from individuals with late puberty or GnRH analog treatment of other indications. Some studies reported that men with constitutionally delayed puberty have decreased BMD in adulthood (95). However, other studies reported that these men have normal BMD (96, 97). Treating adults with GnRH analogs results in a decrease of BMD (98). In children with central precocious puberty, treatment with GnRH analogs has been found to result in a decrease of BMD during treatment by some (99) but not others (100). Studies have reported normal BMD after discontinuing therapy (69, 72, 73, 101, 102). In adolescents treated with growth hormone who are small for gestational age and have normal pubertal timing, 2-year GnRH analog treatments did not adversely affect BMD (103). Calcium supplementation may be beneficial in optimizing bone health in GnRH analog-treated individuals (104). There are no studies of vitamin D supplementation in this context, but clinicians should offer supplements to vitamin D-deficient adolescents. Physical activity, especially during growth, is important for bone mass in healthy individuals (103) and is therefore likely to be beneficial for bone health in GnRH analog-treated subjects.

GnRH analogs did not induce a change in body mass index standard deviation score in GD/gender-incongruent adolescents (94) but caused an increase in fat mass and decrease in lean body mass percentage (92). Studies in girls treated for precocious puberty also reported a stable body mass index standard deviation score during treatment (72) and body mass index and body composition comparable to controls after treatment (73).

Arterial hypertension has been reported as an adverse effect in a few girls treated with GnRH analogs for precocious/early puberty (105, 106). Blood pressure monitoring before and during treatment is recommended.

Individuals may also experience hot flashes, fatigue, and mood alterations as a consequence of pubertal suppression. There is no consensus on treatment of these side effects in this context.

It is recommended that any use of pubertal blockers (and subsequent use of sex hormones, as detailed below) include a discussion about implications for fertility (see recommendation 1.3). Transgender adolescents may

Filed: 10/31/2024

Filed: 01/25/2024

https://academic.oup.com/jcem

want to preserve fertility, which may be otherwise compromised if puberty is suppressed at an early stage and the individual completes phenotypic transition with the use of sex hormones.

Limited data are available regarding the effects of GnRH analogs on brain development. A single cross-sectional study demonstrated no compromise of executive function (107), but animal data suggest there may be an effect of GnRH analogs on cognitive function (108).

Values and preferences

Our recommendation of GnRH analogs places a higher value on the superior efficacy, safety, and reversibility of the pubertal hormone suppression achieved (as compared with the alternatives) and a relatively lower value on limiting the cost of therapy. Of the available alternatives, depot and oral progestin preparations are effective. Experience with this treatment dates back prior to the emergence of GnRH analogs for treating precocious puberty in papers from the 1960s and early 1970s (109–112). These compounds are usually safe, but some side effects have been reported (113-115). Only two recent studies involved transgender youth (116, 117). One of these studies described the use of oral lynestrenol monotherapy followed by the addition of testosterone treatment in transgender boys who were at Tanner stage B4 or further at the start of treatment (117). They found lynestrenol safe, but gonadotropins were not fully suppressed. The study reported metrorrhagia in approximately half of the individuals, mainly in the first 6 months. Acne, headache, hot flashes, and fatigue were other frequent side effects. Another progestin that has been studied in the United States is medroxyprogesterone. This agent is not as effective as GnRH analogs in lowering endogenous sex hormones either and may be associated with other side effects (116). Progestin preparations may be an acceptable treatment for persons without access to GnRH analogs or with a needle phobia. If GnRH analog treatment is not available (insurance denial, prohibitive cost, or other reasons), postpubertal, transgender female adolescents may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see adult section).

Remarks

Page: 21

Page: 96

Measurements of gonadotropin and sex steroid levels give precise information about gonadal axis suppression, although there is insufficient evidence for any specific short-term monitoring scheme in children treated with GnRH analogs (88). If the gonadal axis is not completely suppressed—as evidenced by (for example) menses, erections, or progressive hair growth—the interval of GnRH analog treatment can be shortened or the dose increased. During treatment, adolescents should be monitored for negative effects of delaying puberty, including a halted growth spurt and impaired bone mineral accretion. Table 7 illustrates a suggested clinical protocol.

Anthropometric measurements and X-rays of the left hand to monitor bone age are informative for evaluating growth. To assess BMD, clinicians can perform dualenergy X-ray absorptiometry scans.

- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule (see Table 8) after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years (Table 5). (1 □⊕⊕○○)
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕○○○)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment (Table 9). (2 |⊕⊕○○)

Table 7. Baseline and Follow-Up Protocol During Suppression of Puberty

Every 3-6 mo

Anthropometry: height, weight, sitting height, blood pressure, Tanner stages

Every 6–12 mo

Laboratory: LH, FSH, E2/T, 25OH vitamin D

Every 1-2 y

Bone density using DXA

Bone age on X-ray of the left hand (if clinically indicated)

Table 8. Protocol Induction of Puberty

Case: 24-1714

Case: 24-108

```
Induction of female puberty with oral 17\beta-estradiol, increasing the dose every 6 mo:
  5 μg/kg/d
  10 \mu g/kg/d
  15 \mu g/kg/d
  20 μg/kg/d
  Adult dose = 2-6 \text{ mg/d}
  In postpubertal transgender female adolescents, the dose of 17β-estradiol can be increased more rapidly:
     1 mg/d for 6 mo
     2 mg/d
Induction of female puberty with transdermal 17\beta-estradiol, increasing the dose every 6 mo (new patch is placed every 3.5 d):
  6.25-12.5 \mu g/24 h (cut 25-\mu g patch into quarters, then halves)
  25 μg/24 h
  37.5 μg/24 h
  Adult dose = 50-200 \mu g/24 h
  For alternatives once at adult dose, see Table 11.
  Adjust maintenance dose to mimic physiological estradiol levels (see Table 15).
Induction of male puberty with testosterone esters increasing the dose every 6 mo (IM or SC):
  25 mg/m<sup>2</sup>/2 wk (or alternatively, half this dose weekly, or double the dose every 4 wk)
  50 \text{ mg/m}^2/2 \text{ wk}
  75 mg/m<sup>2</sup>/2 wk
  100 mg/m<sup>2</sup>/2 wk
  Adult dose = 100-200 mg every 2 wk
  In postpubertal transgender male adolescents the dose of testosterone esters can be increased more rapidly:
     75 mg/2 wk for 6 mo
     125 mg/2 wk
  For alternatives once at adult dose, see Table 11.
  Adjust maintenance dose to mimic physiological testosterone levels (see Table 14).
```

Adapted from Hembree et al. (118).

Abbreviations: IM, intramuscularly; SC, subcutaneously.

Evidence

Adolescents develop competence in decision making at their own pace. Ideally, the supervising medical professionals should individually assess this competence, although no objective tools to make such an assessment are currently available.

Many adolescents have achieved a reasonable level of competence by age 15 to 16 years (119), and in many countries 16-year-olds are legally competent with regard to medical decision making (120). However, others believe that although some capacities are generally achieved before age 16 years, other abilities (such as good risk

assessment) do not develop until well after 18 years (121). They suggest that health care procedures should be divided along a matrix of relative risk, so that younger adolescents can be allowed to decide about low-risk procedures, such as most diagnostic tests and common therapies, but not about high-risk procedures, such as most surgical procedures (121).

Currently available data from transgender adolescents support treatment with sex hormones starting at age 16 years (63, 122). However, some patients may incur potential risks by waiting until age 16 years. These include the potential risk to bone health if puberty is suppressed

Table 9. Baseline and Follow-up Protocol During Induction of Puberty

Every 3-6 mo

- •Ånthropometry: height, weight, sitting height, blood pressure, Tanner stages Every 6–12 mo
 - •In transgender males: hemoglobin/hematocrit, lipids, testosterone, 250H vitamin D
 - •In transgender females: prolactin, estradiol, 250H vitamin D

Every 1–2 y

- •BMD using DXA
- •Bone age on X-ray of the left hand (if clinically indicated)

BMD should be monitored into adulthood (until the age of 25–30 y or until peak bone mass has been reached). For recommendations on monitoring once pubertal induction has been completed, see Tables 14 and 15.

Adapted from Hembree et al. (118).

Abbreviation: DXA, dual-energy X-ray absorptiometry.

Filed: 10/31/2024

Document: 78-2

Document: 2-3

Page: 23

doi: 10.1210/jc.2017-01658

https://academic.oup.com/jcem

for 6 to 7 years before initiating sex hormones (*e.g.*, if someone reached Tanner stage 2 at age 9-10 years old). Additionally, there may be concerns about inappropriate height and potential harm to mental health (emotional and social isolation) if initiation of secondary sex characteristics must wait until the person has reached 16 years of age. However, only minimal data supporting earlier use of gender-affirming hormones in transgender adolescents currently exist (63). Clearly, long-term studies are needed to determine the optimal age of sex hormone treatment in GD/gender-incongruent adolescents.

The MHP who has followed the adolescent during GnRH analog treatment plays an essential role in assessing whether the adolescent is eligible to start sex hormone therapy and capable of consenting to this treatment (Table 5). Support of the family/environment is essential. Prior to the start of sex hormones, clinicians should discuss the implications for fertility (see recommendation 1.5). Throughout pubertal induction, an MHP and a pediatric endocrinologist (or other clinician competent in the evaluation and induction of pubertal development) should monitor the adolescent. In addition to monitoring therapy, it is also important to pay attention to general adolescent health issues, including healthy life style choices, such as not smoking, contraception, and appropriate vaccinations (e.g., human papillomavirus).

For the induction of puberty, clinicians can use a similar dose scheme for hypogonadal adolescents with GD/gender incongruence as they use in other individuals with hypogonadism, carefully monitoring for desired and undesired effects (Table 8). In transgender female adolescents, transdermal 17β -estradiol may be an alternative for oral 17β -estradiol. It is increasingly used for pubertal induction in hypogonadal females. However, the absence of low-dose estrogen patches may be a problem. As a result, individuals may need to cut patches to size themselves to achieve appropriate dosing (123). In transgender male adolescents, clinicians can give testosterone injections intramuscularly or subcutaneously (124, 125).

When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion. Gonadotropin secretion and endogenous production of testosterone may resume and interfere with the effectiveness of estrogen treatment, in transgender female adolescents (126, 127). Therefore, continuation of GnRH analog treatment is advised until gonadectomy. Given that GD/gender-incongruent adolescents may opt not to have gonadectomy, long-term studies are necessary to examine the potential risks of prolonged GnRH analog treatment. Alternatively, in transgender male adolescents, GnRH analog treatment can be discontinued once an

adult dose of testosterone has been reached and the individual is well virilized. If uterine bleeding occurs, a progestin can be added. However, the combined use of a GnRH analog (for ovarian suppression) and testosterone may enable phenotypic transition with a lower dose of testosterone in comparison with testosterone alone. If there is a wish or need to discontinue GnRH analog treatment in transgender female adolescents, they may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see section 3.0 "Hormonal Therapy for Transgender Adults").

Values and preferences

The recommendation to initiate pubertal induction only when the individual has sufficient mental capacity (roughly age 16 years) to give informed consent for this partly irreversible treatment places a higher value on the ability of the adolescent to fully understand and oversee the partially irreversible consequences of sex hormone treatment and to give informed consent. It places a lower value on the possible negative effects of delayed puberty. We may not currently have the means to weigh adequately the potential benefits of waiting until around age 16 years to initiate sex hormones vs the potential risks/harm to BMD and the sense of social isolation from having the timing of puberty be so out of sync with peers (128).

Remarks

Before starting sex hormone treatment, effects on fertility and options for fertility preservation should be discussed. Adult height may be a concern in transgender adolescents. In a transgender female adolescent, clinicians may consider higher doses of estrogen or a more rapid tempo of dose escalation during pubertal induction. There are no established treatments yet to augment adult height in a transgender male adolescent with open epiphyses during pubertal induction. It is not uncommon for transgender adolescents to present for clinical services after having completed or nearly completed puberty. In such cases, induction of puberty with sex hormones can be done more rapidly (see Table 8). Additionally, an adult dose of testosterone in transgender male adolescents may suffice to suppress the gonadal axis without the need to use a separate agent. At the appropriate time, the multidisciplinary team should adequately prepare the adolescent for transition to adult care.

3.0 Hormonal Therapy for Transgender Adults

The two major goals of hormonal therapy are (1) to reduce endogenous sex hormone levels, and thus reduce

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869-3903

(129, 130).

the secondary sex characteristics of the individual's designated gender, and (2) to replace endogenous sex hormone levels consistent with the individual's gender identity by using the principles of hormone replacement treatment of hypogonadal patients. The timing of these two goals and the age at which to begin treatment with the sex hormones of the chosen gender is codetermined in collaboration with both the person pursuing transition and the health care providers. The treatment team should include a medical provider knowledgeable in transgender hormone therapy, an MHP knowledgeable in GD/gender incongruence and the mental health concerns of transition, and a primary care provider able to provide care appropriate for

transgender individuals. The physical changes in-

duced by this sex hormone transition are usually ac-

companied by an improvement in mental well-being

- 3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. (1 |⊕⊕⊕○)
- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment (Table 10). (1 □□□□□)
- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 l⊕⊕○○)

Evidence

It is the responsibility of the treating clinician to confirm that the person fulfills criteria for treatment. The treating clinician should become familiar with the terms and criteria presented in Tables 1–5 and take a thorough history from the patient in collaboration with the other members of the treatment team. The treating clinician must ensure that the desire for transition is appropriate; the consequences, risks, and benefits of treatment are well understood; and the desire for transition persists. They also need to discuss fertility preservation options (see recommendation 1.3) (67, 68).

Transgender males

Clinical studies have demonstrated the efficacy of several different androgen preparations to induce masculinization in transgender males (Appendix A) (113, 114, 131–134). Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism (135). Clinicians can use either parenteral or transdermal preparations to achieve testosterone values in the normal male range (this is dependent on the specific assay, but is typically 320 to 1000 ng/dL) (Table 11) (136). Sustained supraphysiologic levels of testosterone increase the risk of adverse reactions (see section 4.0 "Adverse Outcome Prevention and Long-Term Care") and should be avoided.

Similar to androgen therapy in hypogonadal men, testosterone treatment in transgender males results in increased muscle mass and decreased fat mass, increased facial hair and acne, male pattern baldness in those genetically predisposed, and increased sexual desire (137).

Table 10. Medical Risks Associated With Sex Hormone Therapy

Transgender female: estrogen

Very high risk of adverse outcomes:

Thromboembolic disease

Moderate risk of adverse outcomes:

- Macroprolactinoma
- Breast cancer
- Coronary artery disease
- Cerebrovascular disease
- Cholelithiasis
- Hypertriglyceridemia

Transgender male: testosterone

Very high risk of adverse outcomes:

Erythrocytosis (hematocrit > 50%)

Moderate risk of adverse outcomes:

- •Severe liver dysfunction (transaminases > threefold upper limit of normal)
- Coronary artery disease
- Cerebrovascular disease
- Hypertension
- Breast or uterine cancer

Case: 24-1714 Case: 24-108

Document: 78-2 Document: 2-3

Page: 25 Page: 100

Filed: 10/31/2024 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem 3887

Table 11. **Hormone Regimens in Transgender Persons**

Transgender females^a Estrogen Oral Estradiol Transdermal Estradiol transdermal patch (New patch placed every 3-5 d) Parenteral

0.025-0.2 mg/d

Estradiol valerate or cypionate 5-30 mg IM every 2 wk 2-10 mg IM every week

Anti-androgens Spironolactone Cyproterone acetate^b GnRH agonist

100-300 mg/d 25-50 ma/d 3.75 mg SQ (SC) monthly 11.25 mg SQ (SC) 3-monthly

2.0-6.0 mg/d

Transgender males Testosterone Parenteral testosterone Testosterone enanthate or cypionate Testosterone undecanoate^c Transdermal testosterone Testosterone gel 1.6%^d

Testosterone transdermal patch

100-200 mg SQ (IM) every 2 wk or SQ (SC) 50% per week 1000 mg every 12 wk

> 50-100 mg/d 2.5-7.5 mg/d

Abbreviations: IM, intramuscularly; SQ, sequentially; SC, subcutaneously.

In transgender males, testosterone will result in clitoromegaly, temporary or permanent decreased fertility, deepening of the voice, cessation of menses (usually), and a significant increase in body hair, particularly on the face, chest, and abdomen. Cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, clinicians may consider the addition of a progestational agent or endometrial ablation (138). Clinicians may also administer GnRH analogs or depot medroxyprogesterone to stop menses prior to testosterone treatment.

Transgender females

The hormone regimen for transgender females is more complex than the transgender male regimen (Appendix B). Treatment with physiologic doses of estrogen alone is insufficient to suppress testosterone levels into the normal range for females (139). Most published clinical studies report the need for adjunctive therapy to achieve testosterone levels in the female range (21, 113, 114, 132–134, 139, 140).

Multiple adjunctive medications are available, such as progestins with antiandrogen activity and GnRH agonists (141). Spironolactone works by directly blocking androgens during their interaction with the androgen receptor (114, 133, 142). It may also have estrogenic activity (143). Cyproterone acetate, a progestational compound with antiandrogenic properties (113, 132, 144), is widely used in Europe. 5α -Reductase inhibitors do not reduce testosterone levels and have adverse effects (145).

Dittrich et al. (141) reported that monthly doses of the GnRH agonist goserelin acetate in combination with estrogen were effective in reducing testosterone levels with a low incidence of adverse reactions in 60 transgender females. Leuprolide and transdermal estrogen were as effective as cyproterone and transdermal estrogen in a comparative retrospective study (146).

Patients can take estrogen as oral conjugated estrogens, oral 17β -estradiol, or transdermal 17β -estradiol. Among estrogen options, the increased risk of thromboembolic events associated with estrogens in general seems most concerning with ethinyl estradiol specifically (134, 140, 141), which is why we specifically suggest that it not be used in any transgender treatment plan. Data distinguishing among other estrogen options are less well established although there is some thought that oral routes of administration are more thrombogenic due to the "first pass effect" than are transdermal and parenteral routes, and that the risk of thromboembolic events is dose-dependent. Injectable estrogen and sublingual

Appx400

^aEstrogens used with or without antiandrogens or GnRH agonist.

^bNot available in the United States.

^cOne thousand milligrams initially followed by an injection at 6 wk then at 12-wk intervals.

^dAvoid cutaneous transfer to other individuals.

Downloaded from https://academic.oup.com/jcem/article/102/11/3869/4157558 by Yale University, Cushing/Whitney Medical Library user on 04 December 2023

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

estrogen may benefit from avoiding the first pass effect, but they can result in more rapid peaks with greater overall periodicity and thus are more difficult to monitor (147, 148). However, there are no data demonstrating that increased periodicity is harmful otherwise.

Case: 24-1714

Case: 24-108

Clinicians can use serum estradiol levels to monitor oral, transdermal, and intramuscular estradiol. Blood tests cannot monitor conjugated estrogens or synthetic estrogen use. Clinicians should measure serum estradiol and serum testosterone and maintain them at the level for premenopausal females (100 to 200 pg/mL and <50 ng/dL, respectively). The transdermal preparations and injectable estradiol cypionate or valerate preparations may confer an advantage in older transgender females who may be at higher risk for thromboembolic disease (149).

Values

Our recommendation to maintain levels of genderaffirming hormones in the normal adult range places a high value on the avoidance of the long-term complications of pharmacologic doses. Those patients receiving endocrine treatment who have relative contraindications to hormones should have an in-depth discussion with their physician to balance the risks and benefits of therapy.

Remarks

Clinicians should inform all endocrine-treated individuals of all risks and benefits of gender-affirming hormones prior to initiating therapy. Clinicians should strongly encourage tobacco use cessation in transgender females to avoid increased risk of VTE and cardiovascular complications. We strongly discourage the unsupervised use of hormone therapy (150).

Not all individuals with GD/gender incongruence seek treatment as described (e.g., male-to-eunuchs and individuals seeking partial transition). Tailoring current protocols to the individual may be done within the context of accepted safety guidelines using a multidisciplinary approach including mental health. No evidence-based protocols are available for these groups (151). We need prospective studies to better understand treatment options for these persons.

3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 |⊕○○○)

Evidence

Transgender males

Physical changes that are expected to occur during the first 1 to 6 months of testosterone therapy include cessation of menses, increased sexual desire, increased facial and body hair, increased oiliness of skin, increased muscle, and redistribution of fat mass. Changes that occur within the first year of testosterone therapy include deepening of the voice (152, 153), clitoromegaly, and male pattern hair loss (in some cases) (114, 144, 154, 155) (Table 12).

Transgender females

Physical changes that may occur in transgender females in the first 3 to 12 months of estrogen and antiandrogen therapy include decreased sexual desire, decreased spontaneous erections, decreased facial and body hair (usually mild), decreased oiliness of skin, increased breast tissue growth, and redistribution of fat mass (114, 139, 149, 154, 155, 161) (Table 13). Breast development is generally maximal at 2 years after initiating hormones (114, 139, 149, 155). Over a long period of time, the prostate gland and testicles will undergo atrophy.

Although the time course of breast development in transgender females has been studied (150), precise information about other changes induced by sex hormones is lacking (141). There is a great deal of variability among individuals, as evidenced during pubertal development. We all know that a major concern for transgender females is breast development. If we work with estrogens, the result will be often not what the transgender female expects.

Alternatively, there are transgender females who report an anecdotal improved breast development, mood, or sexual desire with the use of progestogens. However, there have been no well-designed studies of the role of progestogens in feminizing hormone regimens, so the question is still open.

Our knowledge concerning the natural history and effects of different cross-sex hormone therapies on breast

Table 12. Masculinizing Effects in Transgender Males

Effect	Onset	Maximum
Skin oiliness/acne	1–6 mo	1–2 y
Facial/body hair growth	6-12 mo	4–5 y
Scalp hair loss	6-12 mo	a'
Increased muscle mass/strength	6-12 mo	2–5 y
Fat redistribution	1–6 mo	2–5 y
Cessation of menses	1–6 mo	b [*]
Clitoral enlargement	1–6 mo	1–2 y
Vaginal atrophy	1–6 mo	1–2 y
Deepening of voice	6–12 mo	1–2 y

Estimates represent clinical observations: Toorians et al. (149), Asscheman et al. (156), Gooren et al. (157), Wierckx et al. (158).

^aPrevention and treatment as recommended for biological men.

^bMenorrhagia requires diagnosis and treatment by a gynecologist.

Case: 24-1714 Document: 78-2 Page: 27 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 102 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3889**

Table 13. Feminizing Effects in Transgender Females

Effect	Onset	Maximum
Redistribution of body fat	3–6 mo	2–3 y
Decrease in muscle mass and strength	3–6 mo	1–2 y
Softening of skin/decreased oiliness	3–6 mo	Unknown
Decreased sexual desire	1–3 mo	3–6 mo
Decreased spontaneous erections	1–3 mo	3–6 mo
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 mo	2–3 y
Decreased testicular volume	3–6 mo	2–3 y
Decreased sperm production	Unknown	>3 y
Decreased terminal hair growth	6–12 mo	>3 y ^a
Scalp hair	Variable	B
Voice changes	None	c

Estimates represent clinical observations: Toorians et al. (149), Asscheman et al. (156), Gooren et al. (157).

development in transgender females is extremely sparse and based on the low quality of evidence. Current evidence does not indicate that progestogens enhance breast development in transgender females, nor does evidence prove the absence of such an effect. This prevents us from drawing any firm conclusion at this moment and demonstrates the need for further research to clarify these important clinical questions (162).

Values and preferences

Transgender persons have very high expectations regarding the physical changes of hormone treatment and are aware that body changes can be enhanced by surgical procedures (*e.g.*, breast, face, and body habitus). Clear expectations for the extent and timing of sex hormone–induced changes may prevent the potential harm and expense of unnecessary procedures.

4.0 Adverse Outcome Prevention and Long-Term Care

Hormone therapy for transgender males and females confers many of the same risks associated with sex hormone replacement therapy in nontransgender persons. The risks arise from and are worsened by inadvertent or intentional use of supraphysiologic doses of sex hormones, as well as use of inadequate doses of sex hormones to maintain normal physiology (131, 139).

4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every

3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. $(2 \mid \oplus \oplus \bigcirc\bigcirc)$

Evidence

Pretreatment screening and appropriate regular medical monitoring are recommended for both transgender males and females during the endocrine transition and periodically thereafter (26, 155). Clinicians should monitor weight and blood pressure, conduct physical exams, and assess routine health questions, such as tobacco use, symptoms of depression, and risk of adverse events such as deep vein thrombosis/pulmonary embolism and other adverse effects of sex steroids.

Transgender males

Table 14 contains a standard monitoring plan for transgender males on testosterone therapy (154, 159). Key issues include maintaining testosterone levels in the physiologic normal male range and avoiding adverse events resulting from excess testosterone therapy, particularly erythrocytosis, sleep apnea, hypertension, excessive weight gain, salt retention, lipid changes, and excessive or cystic acne (135).

Because oral 17-alkylated testosterone is not recommended, serious hepatic toxicity is not anticipated with parenteral or transdermal testosterone use (163, 164). Past concerns regarding liver toxicity with testosterone have been alleviated with subsequent reports that indicate the risk of serious liver disease is minimal (144, 165, 166).

Transgender females

Table 15 contains a standard monitoring plan for transgender females on estrogens, gonadotropin suppression, or antiandrogens (160). Key issues include avoiding supraphysiologic doses or blood levels of estrogen that may lead to increased risk for thromboembolic disease, liver dysfunction, and hypertension. Clinicians should monitor serum estradiol levels using laboratories participating in external quality control, as measurements of estradiol in blood can be very challenging (167).

VTE may be a serious complication. A study reported a 20-fold increase in venous thromboembolic disease in a large cohort of Dutch transgender subjects (161). This increase may have been associated with the use of the synthetic estrogen, ethinyl estradiol (149). The incidence decreased when clinicians stopped administering ethinyl estradiol (161). Thus, the use of synthetic estrogens and conjugated estrogens is undesirable because of the inability to regulate doses by measuring serum levels and the risk of thromboembolic disease. In a German gender clinic, deep vein thrombosis occurred in 1 of 60 of transgender females treated with a GnRH analog and oral

^aComplete removal of male sexual hair requires electrolysis or laser treatment or both.

^bFamilial scalp hair loss may occur if estrogens are stopped.

^cTreatment by speech pathologists for voice training is most effective.

Table 14. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Male

- 1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of virilization and for development of adverse reactions.
- 2. Measure serum testosterone every 3 mo until levels are in the normal physiologic male range:^a
 - a. For testosterone enanthate/cypionate injections, the testosterone level should be measured midway between injections. The target level is 400–700 ng/dL to 400 ng/dL. Alternatively, measure peak and trough levels to ensure levels remain in the normal male range.
 - b. For parenteral testosterone undecanoate, testosterone should be measured just before the following injection. If the level is <400 ng/dL, adjust dosing interval.
 - c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 wk of daily application (at least 2 h after application).
- 3. Measure hematocrit or hemoglobin at baseline and every 3 mo for the first year and then one to two times a year. Monitor weight, blood pressure, and lipids at regular intervals.
- 4. Screening for osteoporosis should be conducted in those who stop testosterone treatment, are not compliant with hormone therapy, or who develop risks for bone loss.
- 5. If cervical tissue is present, monitoring as recommended by the American College of Obstetricians and Gynecologists.
- 6. Ovariectomy can be considered after completion of hormone transition.

Case: 24-1714

Case: 24-108

7. Conduct sub- and periareolar annual breast examinations if mastectomy performed. If mastectomy is not performed, then consider mammograms as recommended by the American Cancer Society.

estradiol (141). The patient who developed a deep vein thrombosis was found to have a homozygous C677 T mutation in the methylenetetrahydrofolate reductase gene. In an Austrian gender clinic, administering genderaffirming hormones to 162 transgender females and 89 transgender males was not associated with VTE, despite an 8.0% and 5.6% incidence of thrombophilia (159). A more recent multinational study reported only 10 cases of VTE from a cohort of 1073 subjects (168). Thrombophilia screening of transgender persons initiating hormone treatment should be restricted to those with a personal or family history of VTE (159). Monitoring D-dimer levels during treatment is not recommended (169).

4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 $\mid \oplus \oplus \bigcirc \bigcirc$)

Evidence

Estrogen therapy can increase the growth of pituitary lactrotroph cells. There have been several reports of prolactinomas occurring after long-term, high-dose estrogen therapy (170–173). Up to 20% of transgender females treated with estrogens may have elevations in prolactin levels associated with enlargement of the pituitary gland (156). In most cases, the serum prolactin levels will return to the normal range with a reduction or discontinuation of the estrogen therapy or discontinuation of cyproterone acetate (157, 174, 175).

The onset and time course of hyperprolactinemia during estrogen treatment are not known. Clinicians should measure prolactin levels at baseline and then at least annually during the transition period and every 2 years thereafter. Given that only a few case studies reported prolactinomas, and prolactinomas were not reported in large cohorts of estrogen-treated persons, the risk is likely to be very low. Because the major presenting findings of microprolactinomas (hypogonadism and sometimes gynecomastia) are not apparent in transgender females, clinicians may perform radiologic examinations of the pituitary in those patients whose prolactin levels persistently increase despite stable or reduced estrogen levels. Some transgender individuals receive psychotropic medications that can increase prolactin levels (174).

Table 15. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Female

- 1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of feminization and for development of adverse reactions.
- 2. Measure serum testosterone and estradiol every 3 mo.
 - a. Serum testosterone levels should be <50 ng/dL.
 - b. Serum estradiol should not exceed the peak physiologic range: 100–200 pg/mL.
- 3. For individuals on spironolactone, serum electrolytes, particularly potassium, should be monitored every 3 mo in the first year and annually thereafter.
- 4. Routine cancer screening is recommended, as in nontransgender individuals (all tissues present).
- 5. Consider BMD testing at baseline (160). In individuals at low risk, screening for osteoporosis should be conducted at age 60 years or in those who are not compliant with hormone therapy.

^aAdapted from Lapauw et al. (154) and Ott et al. (159).

Downloaded from https://academic.oup.com/jcem/article/102/11/3869/4157558 by Yale University, Cushing/Whitney Medical Library user on 04 December 2023

4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 □⊕⊕○○)

Evidence

Transgender males

Administering testosterone to transgender males results in a more atherogenic lipid profile with lowered high-density lipoprotein cholesterol and higher triglyceride and low-density lipoprotein cholesterol values (176–179). Studies of the effect of testosterone on insulin sensitivity have mixed results (178, 180). A randomized, open-label uncontrolled safety study of transgender males treated with testosterone undecanoate demonstrated no insulin resistance after 1 year (181, 182). Numerous studies have demonstrated the effects of sex hormone treatment on the cardiovascular system (160, 179, 183, 184). Long-term studies from The Netherlands found no increased risk for cardiovascular mortality (161). Likewise, a meta-analysis of 19 randomized trials in nontransgender males on testosterone replacement showed no increased incidence of cardiovascular events (185). A systematic review of the literature found that data were insufficient (due to very low-quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or VTE in transgender males (176). Future research is needed to ascertain the potential harm of hormonal therapies (176). Clinicians should manage cardiovascular risk factors as they emerge according to established guidelines (186).

Transgender females

A prospective study of transgender females found favorable changes in lipid parameters with increased high-density lipoprotein and decreased low-density lipoprotein concentrations (178). However, increased weight, blood pressure, and markers of insulin resistance attenuated these favorable lipid changes. In a meta-analysis, only serum triglycerides were higher at ≥24 months without changes in other parameters (187). The largest cohort of transgender females (mean age 41 years, followed for a mean of 10 years) showed no increase in cardiovascular mortality despite a 32% rate of tobacco use (161).

Thus, there is limited evidence to determine whether estrogen is protective or detrimental on lipid and glucose metabolism in transgender females (176). With aging, there is usually an increase of body weight. Therefore, as with nontransgender individuals, clinicians should

monitor and manage glucose and lipid metabolism and blood pressure regularly according to established guidelines (186).

Filed: 10/31/2024

Filed: 01/25/2024

4.4. We recommend that clinicians obtain BMD measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 l⊕⊕○○)

Evidence

Transgender males

Baseline bone mineral measurements in transgender males are generally in the expected range for their pretreatment gender (188). However, adequate dosing of testosterone is important to maintain bone mass in transgender males (189, 190). In one study (190), serum LH levels were inversely related to BMD, suggesting that low levels of sex hormones were associated with bone loss. Thus, LH levels in the normal range may serve as an indicator of the adequacy of sex steroid administration to preserve bone mass. The protective effect of testosterone may be mediated by peripheral conversion to estradiol, both systemically and locally in the bone.

Transgender females

A baseline study of BMD reported T scores less than -2.5 in 16% of transgender females (191). In aging males, studies suggest that serum estradiol more positively correlates with BMD than does testosterone (192, 193) and is more important for peak bone mass (194). Estrogen preserves BMD in transgender females who continue on estrogen and antiandrogen therapies (188, 190, 191, 195, 196).

Fracture data in transgender males and females are not available. Transgender persons who have undergone gonadectomy may choose not to continue consistent sex steroid treatment after hormonal and surgical sex reassignment, thereby becoming at risk for bone loss. There have been no studies to determine whether clinicians should use the sex assigned at birth or affirmed gender for assessing osteoporosis (e.g., when using the FRAX tool). Although some researchers use the sex assigned at birth (with the assumption that bone mass has usually peaked for transgender people who initiate hormones in early adulthood), this should be assessed on a case-by-case basis until there are more data available. This assumption will be further complicated by the increasing prevalence of transgender people who undergo hormonal transition at a pubertal age or soon after puberty. Sex for comparison within risk assessment tools may be based on the age at which hormones were initiated and the length of exposure to hormones. In some cases, it may be 3892 Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

reasonable to assess risk using both the male and female calculators and using an intermediate value. Because all subjects underwent normal pubertal development, with known effects on bone size, reference values for birth sex were used for all participants (154).

Case: 24-108

- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for those designated female at birth. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. $(2 \mid \oplus \bigcirc\bigcirc\bigcirc)$

Evidence

Studies have reported a few cases of breast cancer in transgender females (197-200). A Dutch study of 1800 transgender females followed for a mean of 15 years (range of 1 30 years) found one case of breast cancer. The Women's Health Initiative study reported that females taking conjugated equine estrogen without progesterone for 7 years did not have an increased risk of breast cancer as compared with females taking placebo (137).

In transgender males, a large retrospective study conducted at the U.S. Veterans Affairs medical health system identified seven breast cancers (194). The authors reported that this was not above the expected rate of breast cancers in cisgender females in this cohort. Furthermore, they did report one breast cancer that developed in a transgender male patient after mastectomy, supporting the fact that breast cancer can occur even after mastectomy. Indeed, there have been case reports of breast cancer developing in subareolar tissue in transgender males, which occurred after mastectomy (201, 202).

Women with primary hypogonadism (Turner syndrome) treated with estrogen replacement exhibited a significantly decreased incidence of breast cancer as compared with national standardized incidence ratios (203, 204). These studies suggest that estrogen therapy does not increase the risk of breast cancer in the short term (<20 to 30 years). We need long-term studies to determine the actual risk, as well as the role of screening mammograms. Regular examinations and gynecologic advice should determine monitoring for breast cancer.

Prostate cancer is very rare before the age of 40, especially with androgen deprivation therapy (205). Childhood or pubertal castration results in regression of the prostate and adult castration reverses benign prostate hypertrophy (206). Although van Kesteren et al. (207) reported that estrogen therapy does not induce hypertrophy or premalignant changes in the prostates of transgender females, studies have reported cases of benign prostatic hyperplasia in transgender females treated with estrogens for 20 to 25 years (208, 209). Studies have also reported a few cases of prostate carcinoma in transgender females (210-214).

Transgender females may feel uncomfortable scheduling regular prostate examinations. Gynecologists are not trained to screen for prostate cancer or to monitor prostate growth. Thus, it may be reasonable for transgender females who transitioned after age 20 years to have annual screening digital rectal examinations after age 50 years and prostate-specific antigen tests consistent with U.S. Preventive Services Task Force Guidelines (215).

4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

Evidence

Although aromatization of testosterone to estradiol in transgender males has been suggested as a risk factor for endometrial cancer (216), no cases have been reported. When transgender males undergo hysterectomy, the uterus is small and there is endometrial atrophy (217, 218). Studies have reported cases of ovarian cancer (219, 220). Although there is limited evidence for increased risk of reproductive tract cancers in transgender males, health care providers should determine the medical necessity of a laparoscopic total hysterectomy as part of a genderaffirming surgery to prevent reproductive tract cancer (221).

Values

Given the discomfort that transgender males experience accessing gynecologic care, our recommendation for the medical necessity of total hysterectomy and oophorectomy places a high value on eliminating the risks of female reproductive tract disease and cancer and a lower value on avoiding the risks of these surgical procedures (related to the surgery and to the potential undesirable health consequences of oophorectomy) and their associated costs.

Remarks

The sexual orientation and type of sexual practices will determine the need and types of gynecologic care required following transition. Additionally, in certain countries, the approval required to change the sex in a birth certificate for transgender males may be dependent on having a complete hysterectomy. Clinicians should help patients research nonmedical administrative criteria and Case: 24-1714 Document: 78-2 Page: 31 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 106 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3893**

provide counseling. If individuals decide not to undergo hysterectomy, screening for cervical cancer is the same as all other females.

5.0 Surgery for Sex Reassignment and Gender Confirmation

For many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender role. The type of surgery falls into two main categories: (1) those that directly affect fertility and (2) those that do not. Those that change fertility (previously called sex reassignment surgery) include genital surgery to remove the penis and gonads in the male and removal of the uterus and gonads in the female. The surgeries that effect fertility are often governed by the legal system of the state or country in which they are performed. Other gender-conforming surgeries that do not directly affect fertility are not so tightly governed.

Gender-affirming surgical techniques have improved markedly during the past 10 years. Reconstructive genital surgery that preserves neurologic sensation is now the standard. The satisfaction rate with surgical reassignment of sex is now very high (187). Additionally, the mental health of the individual seems to be improved by participating in a treatment program that defines a pathway of gender-affirming treatment that includes hormones and surgery (130, 144) (Table 16).

Surgery that affects fertility is irreversible. The World Professional Association for Transgender Health Standards of Care (222) emphasizes that the "threshold of 18 should not be seen as an indication in itself for active intervention." If the social transition has not been satisfactory, if the person is not satisfied with or is ambivalent about the effects of sex hormone treatment, or if the person is ambivalent about surgery then the individual should not be referred for surgery (223, 224).

Gender-affirming genital surgeries for transgender females that affect fertility include gonadectomy, penectomy, and creation of a neovagina (225, 226). Surgeons often invert the skin of the penis to form the wall of the vagina, and several literatures reviews have

reported on outcomes (227). Sometimes there is inadequate tissue to form a full neovagina, so clinicians have revisited using intestine and found it to be successful (87, 228, 229). Some newer vaginoplasty techniques may involve autologuous oral epithelial cells (230, 231).

The scrotum becomes the labia majora. Surgeons use reconstructive surgery to fashion the clitoris and its hood, preserving the neurovascular bundle at the tip of the penis as the neurosensory supply to the clitoris. Some surgeons are also creating a sensate pedicled-spot adding a G spot to the neovagina to increase sensation (232). Most recently, plastic surgeons have developed techniques to fashion labia minora. To further complete the feminization, uterine transplants have been proposed and even attempted (233).

Neovaginal prolapse, rectovaginal fistula, delayed healing, vaginal stenosis, and other complications do sometimes occur (234, 235). Clinicians should strongly remind the transgender person to use their dilators to maintain the depth and width of the vagina throughout the postoperative period. Genital sexual responsivity and other aspects of sexual function are usually preserved following genital gender-affirming surgery (236, 237).

Ancillary surgeries for more feminine or masculine appearance are not within the scope of this guideline. Voice therapy by a speech language pathologist is available to transform speech patterns to the affirmed gender (148). Spontaneous voice deepening occurs during testosterone treatment of transgender males (152, 238). No studies have compared the effectiveness of speech therapy, laryngeal surgery, or combined treatment.

Breast surgery is a good example of gender-confirming surgery that does not affect fertility. In all females, breast size exhibits a very broad spectrum. For transgender females to make the best informed decision, clinicians should delay breast augmentation surgery until the patient has completed at least 2 years of estrogen therapy, because the breasts continue to grow during that time (141, 155).

Another major procedure is the removal of facial and masculine-appearing body hair using either electrolysis or

Table 16. Criteria for Gender-Affirming Surgery, Which Affects Fertility

- 1. Persistent, well-documented gender dysphoria
- 2. Legal age of majority in the given country
- 3. Having continuously and responsibly used gender-affirming hormones for 12 mo (if there is no medical contraindication to receiving such therapy)
- 4. Successful continuous full-time living in the new gender role for 12 mo
- 5. If significant medical or mental health concerns are present, they must be well controlled
- 6. Demonstrable knowledge of all practical aspects of surgery (e.g., cost, required lengths of hospitalizations, likely complications, postsurgical rehabilitation)

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

(239-241).

laser treatments. Other feminizing surgeries, such as that to feminize the face, are now becoming more popular

Case: 24-1714

Case: 24-108

In transgender males, clinicians usually delay gender-affirming genital surgeries until after a few years of androgen therapy. Those surgeries that affect fertility in this group include oophorectomy, vaginectomy, and complete hysterectomy. Surgeons can safely perform them vaginally with laparoscopy. These are sometimes done in conjunction with the creation of a neopenis. The cosmetic appearance of a neopenis is now very good, but the surgery is multistage and very expensive (242, 243). Radial forearm flap seems to be the most satisfactory procedure (228, 244). Other flaps also exist (245). Surgeons can make neopenile erections possible by reinervation of the flap and subsequent contraction of the muscle, leading to stiffening of the neopenis (246, 247), but results are inconsistent (248). Surgeons can also stiffen the penis by imbedding some mechanical device (e.g., a rod or some inflatable apparatus) (249, 250). Because of these limitations, the creation of a neopenis has often been less than satisfactory. Recently, penis transplants are being proposed (233).

In fact, most transgender males do not have any external genital surgery because of the lack of access, high cost, and significant potential complications. Some choose a metaoidioplasty that brings forward the clitoris, thereby allowing them to void in a standing position without wetting themselves (251, 252). Surgeons can create the scrotum from the labia majora with good cosmetic effect and can implant testicular prostheses (253).

The most important masculinizing surgery for the transgender male is mastectomy, and it does not affect fertility. Breast size only partially regresses with androgen therapy (155). In adults, discussions about mastectomy usually take place after androgen therapy has started. Because some transgender male adolescents present after significant breast development has occurred, they may also consider mastectomy 2 years after they begin androgen therapy and before age 18 years. Clinicians should individualize treatment based on the physical and mental health status of the individual. There are now newer approaches to mastectomy with better outcomes (254, 255). These often involve chest contouring (256). Mastectomy is often necessary for living comfortably in the new gender (256).

5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically

- necessary and would benefit the patient's overall health and/or well-being. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$
- 5.2. We advise that clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 1⊕○○○)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 l⊕⊕○○).
- 5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 |⊕○○○)

Evidence

Owing to the lack of controlled studies, incomplete follow-up, and lack of valid assessment measures, evaluating various surgical approaches and techniques is difficult. However, one systematic review including a large numbers of studies reported satisfactory cosmetic and functional results for vaginoplasty/neovagina construction (257). For transgender males, the outcomes are less certain. However, the problems are now better understood (258). Several postoperative studies report significant long-term psychological and psychiatric pathology (259-261). One study showed satisfaction with breasts, genitals, and femininity increased significantly and showed the importance of surgical treatment as a key therapeutic option for transgender females (262). Another analysis demonstrated that, despite the young average age at death following surgery and the relatively larger number of individuals with somatic morbidity, the study does not allow for determination of Case: 24-1714 Document: 78-2 Page: 33 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 108 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3895**

causal relationships between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality (263). Reversal surgery in regretful male-to-female transsexuals after sexual reassignment surgery represents a complex, multistage procedure with satisfactory outcomes. Further insight into the characteristics of persons who regret their decision postoperatively would facilitate better future selection of applicants eligible for sexual reassignment surgery. We need more studies with appropriate controls that examine long-term quality of life, psychosocial outcomes, and psychiatric outcomes to determine the long-term benefits of surgical treatment.

When a transgender individual decides to have genderaffirming surgery, both the hormone prescribing clinician and the MHP must certify that the patient satisfies criteria for gender-affirming surgery (Table 16).

There is some concern that estrogen therapy may cause an increased risk for venous thrombosis during or following surgery (176). For this reason, the surgeon and the hormone-prescribing clinician should collaborate in making a decision about the use of hormones before and following surgery. One study suggests that preoperative factors (such as compliance) are less important for patient satisfaction than are the physical postoperative results (56). However, other studies and clinical experience dictate that individuals who do not follow medical instructions and do not work with their physicians toward a common goal do not achieve treatment goals (264) and experience higher rates of postoperative infections and other complications (265, 266). It is also important that the person requesting surgery feels comfortable with the anatomical changes that have occurred during hormone therapy. Dissatisfaction with social and physical outcomes during the hormone transition may be a contraindication to surgery (223).

An endocrinologist or experienced medical provider should monitor transgender individuals after surgery. Those who undergo gonadectomy will require hormone replacement therapy, surveillance, or both to prevent adverse effects of chronic hormone deficiency.

Financial Disclosures of the Task Force*

Wylie C. Hembree (chair)—financial or business/ organizational interests: none declared, significant financial interest or leadership position: none declared. Peggy T. Cohen-Kettenis—financial or business/organizational interests: none declared, significant financial interest or leadership position: none declared. Louis Gooren—financial or business/ organizational interests: none declared, significant financial

interest or leadership position: none declared. Sabine E. Hannema-financial or business/organizational interests: none declared, significant financial interest or leadership position: Ferring Pharmaceuticals Inc. (lecture/conference), Pfizer (lecture). Walter I. Meyer—financial or business/organizational interests: none declared, significant financial interest or leadership position: none declared. M. Hassan Murad**—financial or business/organizational interests: Mayo Clinic, Evidence-based Practice Center, significant financial interest or leadership position: none declared. Stephen M. Rosenthal—financial or business/organizational interests: AbbVie (consultant), National Institutes of Health (grantee), significant financial interest or leadership position: Pediatric Endocrine Society (immediate past president). **Joshua** D. Safer, FACP—financial or business/organizational interests: none declared, significant financial interest or leadership position: none declared. Vin Tangpricha—financial or business/organizational interests: Cystic Fibrosis Foundation (grantee), National Institutes of Health (grantee), significant financial interest or leadership position, Elsevier Journal of Clinical and Translational Endocrinology (editor). Guy G. T'Sjoen—financial or business/organizational interests: none declared, significant financial interest or leadership position: none declared.* Financial, business, and organizational disclosures of the task force cover the year prior to publication. Disclosures prior to this time period are archived.**Evidence-based reviews for this guideline were prepared under contract with the Endocrine Society.

Acknowledgments

Correspondence and Reprint Requests: The Endocrine Society, 2055 L Street NW, Suite 600, Washington, DC 20036. E-mail: publications@endocrine.org; Phone: 202971-3636.

Disclosure Summary: See Financial Disclosures.

Disclaimer: The Endocrine Society's clinical practice guidelines are developed to be of assistance to endocrinologists by providing guidance and recommendations for particular areas of practice. The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The guidelines are not intended to dictate the treatment of a particular patient. Treatment decisions must be made based on the independent judgement of healthcare providers and each patient's individual circumstances.

The Endocrine Society makes no warranty, express or implied, regarding the guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect,

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

special, incidental, or consequential damages related to the use of the information contained herein.

References

- Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S, Guyatt GH, Harbour RT, Haugh MC, Henry D, Hill S, Jaeschke R, Leng G, Liberati A, Magrini N, Mason J, Middleton P, Mrukowicz J, O'Connell D, Oxman AD, Phillips B, Schünemann HJ, Edejer T, Varonen H, Vist GE, Williams JW, Jr, Zaza S; GRADE Working Group. Grading quality of evidence and strength of recommendations. BMJ. 2004;328(7454):1490.
- Swiglo BA, Murad MH, Schünemann HJ, Kunz R, Vigersky RA, Guyatt GH, Montori VM. A case for clarity, consistency, and helpfulness: state-of-the-art clinical practice guidelines in endocrinology using the grading of recommendations, assessment, development, and evaluation system. J Clin Endocrinol Metab. 2008;93(3):666–673.
- Bullough VL. Transsexualism in history. Arch Sex Behav. 1975; 4(5):561–571.
- 4. Benjamin H. The transsexual phenomenon. *Trans N Y Acad Sci.* 1967;29(4):428–430.
- Meyerowitz J. How Sex Changed: A History of Transsexuality in the United States. Cambridge, MA: Harvard University Press; 2002.
- Hirschfeld M. Was muss das Volk vom Dritten Geschlecht wissen. Verlag Max Spohr, Leipzig; 1901.
- Fisk NM. Editorial: Gender dysphoria syndrome—the conceptualization that liberalizes indications for total gender reorientation and implies a broadly based multi-dimensional rehabilitative regimen. West J Med. 1974;120(5):386–391.
- Diamond L. Transgender experience and identity. In: Schwartz SJ, Luyckx K, Vignoles VL, eds. *Handbook of Identity Theory and Research*. New York, NY: Springer; 2011:629–647.
- Queen C, Schimel L, eds. PoMoSexuals: Challenging Assumptions About Gender and Sexuality. San Francisco, CA: Cleis Press; 1997
- Case LK, Ramachandran VS. Alternating gender incongruity: a new neuropsychiatric syndrome providing insight into the dynamic plasticity of brain-sex. *Med Hypotheses*. 2012;78(5): 626–631.
- Johnson TW, Wassersug RJ. Gender identity disorder outside the binary: when gender identity disorder-not otherwise specified is not good enough. *Arch Sex Behav.* 2010;39(3):597–598.
- Wibowo E, Wassersug R, Warkentin K, Walker L, Robinson J, Brotto L, Johnson T. Impact of androgen deprivation therapy on sexual function: a response. *Asian J Androl*. 2012;14(5):793–794.
- Pasquesoone V. 7 countries giving transgender people fundamental rights the U.S. still won't. 2014. Available at: https://mic.com/articles/ 87149/7-countries-giving-transgender-people-fundamental-rights-theu-s-still-won-t. Accessed 26 August 2016.
- American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Association Publishing.
- Drescher J, Cohen-Kettenis P, Winter S. Minding the body: situating gender identity diagnoses in the ICD-11. *Int Rev Psychiatry*. 2012;24(6):568–577.
- 16. World Professional Association for Transgender Health. Standards of care for the health of transsexual, transgender, and gender nonconforming people. Available at: http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351&pk_association_webpage=3926. Accessed 1 September 2017.
- 17. Kreukels BP, Haraldsen IR, De Cuypere G, Richter-Appelt H, Gijs L, Cohen-Kettenis PT. A European network for the investigation of gender incongruence: the ENIGI initiative. *Eur Psychiatry*. 2012;27(6):445–450.

- Dekker MJ, Wierckx K, Van Caenegem E, Klaver M, Kreukels BP, Elaut E, Fisher AD, van Trotsenburg MA, Schreiner T, den Heijer M, T'Sjoen G. A European network for the investigation of gender incongruence: endocrine part. J Sex Med. 2016;13(6):994–999.
- Ruble DN, Martin CL, Berenbaum SA. Gender development. In: Damon WL, Lerner RM, Eisenberg N, eds. *Handbook of Child Psychology: Social, Emotional, and Personality Development*. Vol. 3. 6th ed. New York, NY: Wiley; 2006;858–931.
- Steensma TD, Kreukels BP, de Vries AL, Cohen-Kettenis PT. Gender identity development in adolescence. *Horm Behav*. 2013; 64(2):288–297.
- Rosenthal SM. Approach to the patient: transgender youth: endocrine considerations. J Clin Endocrinol Metab. 2014;99(12): 4379–4389.
- Saraswat A, Weinand JD, Safer JD. Evidence supporting the biologic nature of gender identity. *Endocr Pract.* 2015;21(2): 199–204.
- 23. Gooren L. The biology of human psychosexual differentiation. *Horm Behav.* 2006;50(4):589–601.
- 24. Berenbaum SA, Meyer-Bahlburg HF. Gender development and sexuality in disorders of sex development. *Horm Metab Res.* 2015; 47(5):361–366.
- Dessens AB, Slijper FME, Drop SLS. Gender dysphoria and gender change in chromosomal females with congenital adrenal hyperplasia. *Arch Sex Behav.* 2005;34(4):389–397.
- Meyer-Bahlburg HFL, Dolezal C, Baker SW, Ehrhardt AA, New MI. Gender development in women with congenital adrenal hyperplasia as a function of disorder severity. *Arch Sex Behav*. 2006; 35(6):667–684.
- 27. Frisén L, Nordenström A, Falhammar H, Filipsson H, Holmdahl G, Janson PO, Thorén M, Hagenfeldt K, Möller A, Nordenskjöld A. Gender role behavior, sexuality, and psychosocial adaptation in women with congenital adrenal hyperplasia due to CYP21A2 deficiency. *J Clin Endocrinol Metab*. 2009;94(9):3432–3439.
- 28. Meyer-Bahlburg HFL, Dolezal C, Baker SW, Carlson AD, Obeid JS, New MI. Prenatal androgenization affects gender-related behavior but not gender identity in 5–12-year-old girls with congenital adrenal hyperplasia. *Arch Sex Behav*. 2004;33(2):97–104.
- Cohen-Kettenis PT. Gender change in 46,XY persons with 5α-reductase-2 deficiency and 17β-hydroxysteroid dehydrogenase-3 deficiency. Arch Sex Behav. 2005;34(4):399–410.
- 30. Reiner WG, Gearhart JP. Discordant sexual identity in some genetic males with cloacal exstrophy assigned to female sex at birth. *N Engl J Med*. 2004;350(4):333–341.
- 31. Meyer-Bahlburg HFL. Gender identity outcome in female-raised 46,XY persons with penile agenesis, cloacal exstrophy of the bladder, or penile ablation. *Arch Sex Behav*. 2005;34(4):423–438.
- 32. Coolidge FL, Thede LL, Young SE. The heritability of gender identity disorder in a child and adolescent twin sample. *Behav Genet*. 2002;32(4):251–257.
- 33. Heylens G, De Cuypere G, Zucker KJ, Schelfaut C, Elaut E, Vanden Bossche H, De Baere E, T'Sjoen G. Gender identity disorder in twins: a review of the case report literature. *J Sex Med*. 2012;9(3):751–757.
- 34. Fernández R, Esteva I, Gómez-Gil E, Rumbo T, Almaraz MC, Roda E, Haro-Mora J-J, Guillamón A, Pásaro E. Association study of ERβ, AR, and CYP19A1 genes and MtF transsexualism. *J Sex Med.* 2014;11(12):2986–2994.
- Henningsson S, Westberg L, Nilsson S, Lundström B, Ekselius L, Bodlund O, Lindström E, Hellstrand M, Rosmond R, Eriksson E, Landén M. Sex steroid-related genes and male-to-female transsexualism. *Psychoneuroendocrinology*. 2005;30(7):657–664.
- Hare L, Bernard P, Sánchez FJ, Baird PN, Vilain E, Kennedy T, Harley VR. Androgen receptor repeat length polymorphism associated with male-to-female transsexualism. *Biol Psychiatry*. 2009;65(1):93–96.
- Lombardo F, Toselli L, Grassetti D, Paoli D, Masciandaro P,
 Valentini F, Lenzi A, Gandini L. Hormone and genetic study in

Case: 24-1714 Document: 78-2 Page: 35 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 110 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3897**

male to female transsexual patients. *J Endocrinol Invest.* 2013; 36(8):550–557.

- Ujike H, Otani K, Nakatsuka M, Ishii K, Sasaki A, Oishi T, Sato T, Okahisa Y, Matsumoto Y, Namba Y, Kimata Y, Kuroda S. Association study of gender identity disorder and sex hormone-related genes. *Prog Neuropsychopharmacol Biol Psychiatry*. 2009;33(7):1241–1244.
- 39. Kreukels BP, Guillamon A. Neuroimaging studies in people with gender incongruence. *Int Rev Psychiatry*. 2016;28(1): 120–128.
- Steensma TD, Biemond R, de Boer F, Cohen-Kettenis PT. Desisting and persisting gender dysphoria after childhood: a qualitative follow-up study. Clin Child Psychol Psychiatry. 2011;16(4):499–516.
- Wallien MSC, Cohen-Kettenis PT. Psychosexual outcome of gender-dysphoric children. J Am Acad Child Adolesc Psychiatry. 2008;47(12):1413–1423.
- Steensma TD, McGuire JK, Kreukels BPC, Beekman AJ, Cohen-Kettenis PT. Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study. J Am Acad Child Adolesc Psychiatry. 2013;52(6):582–590.
- Cohen-Kettenis PT, Owen A, Kaijser VG, Bradley SJ, Zucker KJ. Demographic characteristics, social competence, and behavior problems in children with gender identity disorder: a crossnational, cross-clinic comparative analysis. *J Abnorm Child Psychol.* 2003;31(1):41–53.
- 44. Dhejne C, Van Vlerken R, Heylens G, Arcelus J. Mental health and gender dysphoria: a review of the literature. *Int Rev Psychiatry*. 2016;28(1):44–57.
- Pasterski V, Gilligan L, Curtis R. Traits of autism spectrum disorders in adults with gender dysphoria. Arch Sex Behav. 2014; 43(2):387–393.
- Spack NP, Edwards-Leeper L, Feldman HA, Leibowitz S, Mandel F, Diamond DA, Vance SR. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418–425.
- Terada S, Matsumoto Y, Sato T, Okabe N, Kishimoto Y, Uchitomi Y. Factors predicting psychiatric co-morbidity in gender-dysphoric adults. *Psychiatry Res.* 2012;200(2-3):469–474.
- VanderLaan DP, Leef JH, Wood H, Hughes SK, Zucker KJ. Autism spectrum disorder risk factors and autistic traits in gender dysphoric children. J Autism Dev Disord. 2015;45(6):1742–1750.
- de Vries ALC, Doreleijers TAH, Steensma TD, Cohen-Kettenis PT. Psychiatric comorbidity in gender dysphoric adolescents. *J Child Psychol Psychiatry*. 2011;52(11):1195–1202.
- de Vries ALC, Noens ILJ, Cohen-Kettenis PT, van Berckelaer-Onnes IA, Doreleijers TA. Autism spectrum disorders in gender dysphoric children and adolescents. *J Autism Dev Disord*. 2010; 40(8):930–936.
- Wallien MSC, Swaab H, Cohen-Kettenis PT. Psychiatric comorbidity among children with gender identity disorder. J Am Acad Child Adolesc Psychiatry. 2007;46(10):1307–1314.
- Kuiper AJ, Cohen-Kettenis PT. Gender role reversal among postoperative transsexuals. Available at: https://www.atria.nl/ ezines/web/IJT/97-03/numbers/symposion/ijtc0502.htm. Accessed 26 August 2016.
- Landén M, Wålinder J, Hambert G, Lundström B. Factors predictive of regret in sex reassignment. *Acta Psychiatr Scand*. 1998; 97(4):284–289.
- Olsson S-E, Möller A. Regret after sex reassignment surgery in a male-to-female transsexual: a long-term follow-up. *Arch Sex Behav.* 2006;35(4):501–506.
- Pfäfflin F, Junge A, eds. Geschlechtsumwandlung: Abhandlungen zur Transsexualität. Stuttgart, Germany: Schattauer; 1992.
- Lawrence AA. Factors associated with satisfaction or regret following male-to-female sex reassignment surgery. *Arch Sex Behav*. 2003;32(4):299–315.

- Cohen-Kettenis PT, Pfäfflin F. Transgenderism and Intersexuality in Childhood and Adolescence: Making Choices. Thousand Oaks, CA: SAGE Publications; 2003.
- 58. Di Ceglie D, Freedman D, McPherson S, Richardson P. Children and adolescents referred to a specialist gender identity development service: clinical features and demographic characteristics. Available at: https://www.researchgate.net/publication/276061306_Children_and_Adolescents_Referred_to_a_Specialist_Gender_Identity_Development_Service_Clinical_Features_and_Demographic_Characteristics. Accessed 20 July 2017.
- 59. Gijs L, Brewaeys A. Surgical treatment of gender dysphoria in adults and adolescents: recent developments, effectiveness, and challenges. *Annu Rev Sex Res.* 2007;18:178–224.
- Cohen-Kettenis PT, van Goozen SHM. Sex reassignment of adolescent transsexuals: a follow-up study. J Am Acad Child Adolesc Psychiatry. 1997;36(2):263–271.
- 61. Smith YLS, van Goozen SHM, Cohen-Kettenis PT. Adolescents with gender identity disorder who were accepted or rejected for sex reassignment surgery: a prospective follow-up study. *J Am Acad Child Adolesc Psychiatry*. 2001;40(4):472–481.
- Smith YLS, Van Goozen SHM, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals. *Psychol Med.* 2005;35(1):89–99.
- 63. de Vries ALC, McGuire JK, Steensma TD, Wagenaar ECF, Doreleijers TAH, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. 2014;134(4):696–704.
- Cole CM, O'Boyle M, Emory LE, Meyer WJ III. Comorbidity of gender dysphoria and other major psychiatric diagnoses. *Arch Sex Behav.* 1997;26(1):13–26.
- Cohen-Kettenis PT, Schagen SEE, Steensma TD, de Vries ALC, Delemarre-van de Waal HA. Puberty suppression in a genderdysphoric adolescent: a 22-year follow-up. *Arch Sex Behav*. 2011; 40(4):843–847.
- 66. First MB. Desire for amputation of a limb: paraphilia, psychosis, or a new type of identity disorder. *Psychol Med.* 2005;35(6): 919–928.
- 67. Wierckx K, Van Caenegem E, Pennings G, Elaut E, Dedecker D, Van de Peer F, Weyers S, De Sutter P, T'Sjoen G. Reproductive wish in transsexual men. *Hum Reprod*. 2012;27(2):483–487.
- Wierckx K, Stuyver I, Weyers S, Hamada A, Agarwal A, De Sutter P, T'Sjoen G. Sperm freezing in transsexual women. *Arch Sex Behav.* 2012;41(5):1069–1071.
- 69. Bertelloni S, Baroncelli GI, Ferdeghini M, Menchini-Fabris F, Saggese G. Final height, gonadal function and bone mineral density of adolescent males with central precocious puberty after therapy with gonadotropin-releasing hormone analogues. Eur J Pediatr. 2000;159(5):369–374.
- Büchter D, Behre HM, Kliesch S, Nieschlag E. Pulsatile GnRH or human chorionic gonadotropin/human menopausal gonadotropin as effective treatment for men with hypogonadotropic hypogonadism: a review of 42 cases. *Eur J Endocrinol*. 1998; 139(3):298–303.
- Liu PY, Turner L, Rushford D, McDonald J, Baker HW, Conway AJ, Handelsman DJ. Efficacy and safety of recombinant human follicle stimulating hormone (Gonal-F) with urinary human chorionic gonadotrophin for induction of spermatogenesis and fertility in gonadotrophin-deficient men. *Hum Reprod.* 1999; 14(6):1540–1545.
- 72. Pasquino AM, Pucarelli I, Accardo F, Demiraj V, Segni M, Di Nardo R. Long-term observation of 87 girls with idiopathic central precocious puberty treated with gonadotropin-releasing hormone analogs: impact on adult height, body mass index, bone mineral content, and reproductive function. *J Clin Endocrinol Metab.* 2008;93(1):190–195.
- Magiakou MA, Manousaki D, Papadaki M, Hadjidakis D, Levidou G, Vakaki M, Papaefstathiou A, Lalioti N, Kanaka-Gantenbein C, Piaditis G, Chrousos GP, Dacou-Voutetakis C. The

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869-3903

efficacy and safety of gonadotropin-releasing hormone analog treatment in childhood and adolescence: a single center, long-term

follow-up study. J Clin Endocrinol Metab. 2010;95(1):109-117.

- Baba T, Endo T, Honnma H, Kitajima Y, Hayashi T, Ikeda H, Masumori N, Kamiya H, Moriwaka O, Saito T. Association between polycystic ovary syndrome and female-to-male transsexuality. *Hum Reprod*. 2007;22(4):1011–1016.
- 75. Spinder T, Spijkstra JJ, van den Tweel JG, Burger CW, van Kessel H, Hompes PGA, Gooren LJG. The effects of long term testosterone administration on pulsatile luteinizing hormone secretion and on ovarian histology in eugonadal female to male transsexual subjects. J Clin Endocrinol Metab. 1989;69(1):151–157.
- Baba T, Endo T, Ikeda K, Shimizu A, Honnma H, Ikeda H, Masumori N, Ohmura T, Kiya T, Fujimoto T, Koizumi M, Saito T. Distinctive features of female-to-male transsexualism and prevalence of gender identity disorder in Japan. *J Sex Med*. 2011; 8(6):1686–1693.
- Vujovic S, Popovic S, Sbutega-Milosevic G, Djordjevic M, Gooren L. Transsexualism in Serbia: a twenty-year follow-up study. *J Sex Med.* 2009;6(4):1018–1023.
- Ikeda K, Baba T, Noguchi H, Nagasawa K, Endo T, Kiya T, Saito T. Excessive androgen exposure in female-to-male transsexual persons of reproductive age induces hyperplasia of the ovarian cortex and stroma but not polycystic ovary morphology. *Hum Reprod.* 2013;28(2):453–461.
- Trebay G. He's pregnant. You're speechles. New York Times. 22 June 2008.
- Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. Obstet Gynecol. 2014;124(6):1120–1127.
- 81. De Sutter P. Donor inseminations in partners of female-to-male transsexuals: should the question be asked? *Reprod Biomed Online*. 2003;6(3):382, author reply 282–283.
- 82. De Roo C, Tilleman K, T'Sjoen G, De Sutter P. Fertility options in transgender people. *Int Rev Psychiatry*. 2016;28(1):112–119.
- 83. Wennink JMB, Delemarre-van de Waal HA, Schoemaker R, Schoemaker H, Schoemaker J. Luteinizing hormone and follicle stimulating hormone secretion patterns in boys throughout puberty measured using highly sensitive immunoradiometric assays. *Clin Endocrinol (Oxf)*. 1989;31(5):551–564.
- Cohen-Kettenis PT, Delemarre-van de Waal HA, Gooren LJG. The treatment of adolescent transsexuals: changing insights. J Sex Med. 2008;5(8):1892–1897.
- Delemarre-van de Waal HA, Cohen-Kettenis PT. Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects. Eur J Endocrinol. 2006;155:S131–S137.
- de Vries ALC, Steensma TD, Doreleijers TAH, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. J Sex Med. 2011;8(8):2276–2283.
- 87. Bouman MB, van Zeijl MCT, Buncamper ME, Meijerink WJHJ, van Bodegraven AA, Mullender MG. Intestinal vaginoplasty revisited: a review of surgical techniques, complications, and sexual function. J Sex Med. 2014;11(7):1835–1847.
- 88. Carel JC, Eugster EA, Rogol A, Ghizzoni L, Palmert MR, Antoniazzi F, Berenbaum S, Bourguignon JP, Chrousos GP, Coste J, Deal S, de Vries L, Foster C, Heger S, Holland J, Jahnukainen K, Juul A, Kaplowitz P, Lahlou N, Lee MM, Lee P, Merke DP, Neely EK, Oostdijk W, Phillip M, Rosenfield RL, Shulman D, Styne D, Tauber M, Wit JM; ESPE-LWPES GnRH Analogs Consensus Conference Group. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123(4):e752–e762.
- Roth CL, Brendel L, Rückert C, Hartmann K. Antagonistic and agonistic GnRH analogue treatment of precocious puberty: tracking gonadotropin concentrations in urine. *Horm Res.* 2005; 63(5):257–262.

- 90. Roth C. Therapeutic potential of GnRH antagonists in the treatment of precocious puberty. *Expert Opin Investig Drugs*. 2002;11(9):1253–1259.
- 91. Tuvemo T. Treatment of central precocious puberty. *Expert Opin Investig Drugs*. 2006;15(5):495–505.
- Schagen SE, Cohen-Kettenis PT, Delemarre-van de Waal HA, Hannema SE. Efficacy and safety of gonadotropin-releasing hormone agonist treatment to suppress puberty in gender dysphoric adolescents. *J Sex Med.* 2016;13(7):1125–1132.
- Manasco PK, Pescovitz OH, Feuillan PP, Hench KD, Barnes KM, Jones J, Hill SC, Loriaux DL, Cutler GB, Jr. Resumption of puberty after long term luteinizing hormone-releasing hormone agonist treatment of central precocious puberty. *J Clin Endocrinol Metab*. 1988;67(2):368–372.
- 94. Klink D, Caris M, Heijboer A, van Trotsenburg M, Rotteveel J. Bone mass in young adulthood following gonadotropin-releasing hormone analog treatment and cross-sex hormone treatment in adolescents with gender dysphoria. *J Clin Endocrinol Metab*. 2015;100(2):E270–E275.
- Finkelstein JS, Klibanski A, Neer RM. A longitudinal evaluation of bone mineral density in adult men with histories of delayed puberty. J Clin Endocrinol Metab. 1996;81(3):1152–1155.
- Bertelloni S, Baroncelli GI, Ferdeghini M, Perri G, Saggese G. Normal volumetric bone mineral density and bone turnover in young men with histories of constitutional delay of puberty. *J Clin Endocrinol Metab.* 1998;83(12):4280–4283.
- 97. Darelid A, Ohlsson C, Nilsson M, Kindblom JM, Mellström D, Lorentzon M. Catch up in bone acquisition in young adult men with late normal puberty. *J Bone Miner Res.* 2012;27(10): 2198–2207.
- 98. Mittan D, Lee S, Miller E, Perez RC, Basler JW, Bruder JM. Bone loss following hypogonadism in men with prostate cancer treated with GnRH analogs. *J Clin Endocrinol Metab.* 2002;87(8): 3656–3661.
- Saggese G, Bertelloni S, Baroncelli GI, Battini R, Franchi G. Reduction of bone density: an effect of gonadotropin releasing hormone analogue treatment in central precocious puberty. *Eur J Pediatr.* 1993;152(9):717–720.
- Neely EK, Bachrach LK, Hintz RL, Habiby RL, Slemenda CW, Feezle L, Pescovitz OH. Bone mineral density during treatment of central precocious puberty. *J Pediatr*. 1995;127(5):819–822.
- 101. Bertelloni S, Baroncelli GI, Sorrentino MC, Perri G, Saggese G. Effect of central precocious puberty and gonadotropin-releasing hormone analogue treatment on peak bone mass and final height in females. Eur J Pediatr. 1998;157(5):363–367.
- 102. Thornton P, Silverman LA, Geffner ME, Neely EK, Gould E, Danoff TM. Review of outcomes after cessation of gonadotropin-releasing hormone agonist treatment of girls with precocious puberty. *Pediatr Endocrinol Rev.* 2014;11(3):306–317.
- 103. Lem AJ, van der Kaay DC, Hokken-Koelega AC. Bone mineral density and body composition in short children born SGA during growth hormone and gonadotropin releasing hormone analog treatment. J Clin Endocrinol Metab. 2013;98(1):77–86.
- 104. Antoniazzi F, Zamboni G, Bertoldo F, Lauriola S, Mengarda F, Pietrobelli A, Tatò L. Bone mass at final height in precocious puberty after gonadotropin-releasing hormone agonist with and without calcium supplementation. *J Clin Endocrinol Metab*. 2003;88(3):1096–1101.
- Calcaterra V, Mannarino S, Corana G, Codazzi AC, Mazzola A, Brambilla P, Larizza D. Hypertension during therapy with triptorelin in a girl with precocious puberty. *Indian J Pediatr*. 2013; 80(10):884–885.
- Siomou E, Kosmeri C, Pavlou M, Vlahos AP, Argyropoulou MI, Siamopoulou A. Arterial hypertension during treatment with triptorelin in a child with Williams-Beuren syndrome. *Pediatr Nephrol.* 2014;29(9):1633–1636.
- Staphorsius AS, Kreukels BPC, Cohen-Kettenis PT, Veltman DJ, Burke SM, Schagen SEE, Wouters FM, Delemarre-van de Waal

Case: 24-1714 Document: 78-2 Page: 37 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 112 Filed: 01/25/2024

doi: 10.1210/jc.2017-01658 https://academic.oup.com/jcem **3899**

HA, Bakker J. Puberty suppression and executive functioning: an fMRI-study in adolescents with gender dysphoria. *Psychoneuroendocrinology*. 2015;56:190–199.

- 108. Hough D, Bellingham M, Haraldsen IR, McLaughlin M, Rennie M, Robinson JE, Solbakk AK, Evans NP. Spatial memory is impaired by peripubertal GnRH agonist treatment and testosterone replacement in sheep. *Psychoneuroendocrinology*. 2017; 75:173–182.
- Collipp PJ, Kaplan SA, Boyle DC, Plachte F, Kogut MD. Constitutional Isosexual Precocious Puberty. Am J Dis Child. 1964; 108:399–405.
- Hahn HB, Jr, Hayles AB, Albert A. Medroxyprogesterone and constitutional precocious puberty. Mayo Clin Proc. 1964;39: 182–190.
- 111. Kaplan SA, Ling SM, Irani NG. Idiopathic isosexual precocity. *Am J Dis Child*. 1968;116(6):591–598.
- 112. Schoen EJ. Treatment of idiopathic precocious puberty in boys. *J Clin Endocrinol Metab.* 1966;26(4):363–370.
- 113. Gooren L. Hormone treatment of the adult transsexual patient. *Horm Res.* 2005;64(Suppl 2):31–36.
- 114. Moore E, Wisniewski A, Dobs A. Endocrine treatment of transsexual people: a review of treatment regimens, outcomes, and adverse effects. J Clin Endocrinol Metab. 2003;88(8):3467–3473.
- 115. Krueger RB, Hembree W, Hill M. Prescription of medroxyprogesterone acetate to a patient with pedophilia, resulting in Cushing's syndrome and adrenal insufficiency. Sex Abuse. 2006; 18(2):227–228.
- 116. Lynch MM, Khandheria MM, Meyer WJ. Retrospective study of the management of childhood and adolescent gender identity disorder using medroxyprogesterone acetate. *Int J Transgenderism.* 2015;16:201–208.
- 117. Tack LJW, Craen M, Dhondt K, Vanden Bossche H, Laridaen J, Cools M. Consecutive lynestrenol and cross-sex hormone treatment in biological female adolescents with gender dysphoria: a retrospective analysis. *Biol Sex Differ*. 2016;7:14.
- 118. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, Gooren LJ, Meyer WJ 3rd, Spack NP, Tangpricha V, Montori VM; Endocrine Society. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94(9):3132–3154.
- Mann L, Harmoni R, Power C. Adolescent decision-making: the development of competence. J Adolesc. 1989;12(3):265–278.
- Stultiëns L, Goffin T, Borry P, Dierickx K, Nys H. Minors and informed consent: a comparative approach. Eur J Health Law. 2007;14(1):21–46.
- 121. Arshagouni P. "But I'm an adult now ... sort of". Adolescent consent in health care decision-making and the adolescent brain. Available at: http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1124&context=jhclp. Accessed 25 June 2017.
- 122. NHS. Prescribing of cross-sex hormones as part of the gender identity development service for children and adolescents. Available at: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/clinical-com-pol-16046p.pdf. Accessed 14 June 2017.
- 123. Ankarberg-Lindgren C, Kriström B, Norjavaara E. Physiological estrogen replacement therapy for puberty induction in girls: a clinical observational study. *Horm Res Paediatr*. 2014;81(4): 239–244.
- 124. Olson J, Schrager SM, Clark LF, Dunlap SL, Belzer M. Subcutaneous testosterone: an effective delivery mechanism for masculinizing young transgender men. *LGBT Health*. 2014;1(3): 165–167.
- 125. Spratt DI, Stewart I, Savage C, Craig W, Spack NP, Chandler DW, Spratt LV, Eimicke T, Olshan JS. Subcutaneous injection of testosterone is an effective and preferred alternative to intramuscular injection: demonstration in female-to-male transgender patients. J Clin Endocrinol Metab. 2017. doi:10.1210/jc.2017-00359

- 126. Eisenegger C, von Eckardstein A, Fehr E, von Eckardstein S. Pharmacokinetics of testosterone and estradiol gel preparations in healthy young men. *Psychoneuroendocrinology*. 2013;38(2): 171–178.
- 127. de Ronde W, ten Kulve J, Woerdeman J, Kaufman J-M, de Jong FH. Effects of oestradiol on gonadotrophin levels in normal and castrated men. *Clin Endocrinol (Oxf)*. 2009;71(6):874–879.
- Money J, Ehrhardt A. Man & woman, boy & girl: differentiation and dimorphism of gender identity from conception to maturity. Baltimore, MD: Johns Hopkins University Press; 1972:202–206.
- 129. Heylens G, Verroken C, De Cock S, T'Sjoen G, De Cuypere G. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. *J Sex Med.* 2014;11(1):119–126.
- Costa R, Colizzi M. The effect of cross-sex hormonal treatment on gender dysphoria individuals' mental health: a systematic review. Neuropsychiatr Dis Treat. 2016;12:1953–1966.
- 131. Gooren LJG, Giltay EJ. Review of studies of androgen treatment of female-to-male transsexuals: effects and risks of administration of androgens to females. J Sex Med. 2008;5(4):765–776.
- 132. Levy A, Crown A, Reid R. Endocrine intervention for transsexuals. *Clin Endocrinol (Oxf)*. 2003;**59**(4):409–418.
- 133. Tangpricha V, Ducharme SH, Barber TW, Chipkin SR. Endocrinologic treatment of gender identity disorders. *Endocr Pract*. 2003;9(1):12–21.
- 134. Meriggiola MC, Gava G. Endocrine care of transpeople part I. A review of cross-sex hormonal treatments, outcomes and adverse effects in transmen. Clin Endocrinol (Oxf). 2015;83(5):597–606.
- 135. Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM. Testosterone therapy in adult men with androgen deficiency syndromes: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2006;91(6): 1995–2010.
- 136. Pelusi C, Costantino A, Martelli V, Lambertini M, Bazzocchi A, Ponti F, Battista G, Venturoli S, Meriggiola MC. Effects of three different testosterone formulations in female-to-male transsexual persons. *J Sex Med.* 2014;11(12):3002–3011.
- 137. Anderson GL, Limacher M, Assaf AR, Bassford T, Beresford SA, Black H, Bonds D, Brunner R, Brzyski R, Caan B, Chlebowski R, Curb D, Gass M, Hays J, Heiss G, Hendrix S, Howard BV, Hsia J, Hubbell A, Jackson R, Johnson KC, Judd H, Kotchen JM, Kuller L, LaCroix AZ, Lane D, Langer RD, Lasser N, Lewis CE, Manson J, Margolis K, Ockene J, O'Sullivan MJ, Phillips L, Prentice RL, Ritenbaugh C, Robbins J, Rossouw JE, Sarto G, Stefanick ML, Van Horn L, Wactawski-Wende J, Wallace R, Wassertheil-Smoller S; Women's Health Initiative Steering Committee. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy: the Women's Health Initiative randomized controlled trial. JAMA. 2004;291(14):1701–1712.
- 138. Dickersin K, Munro MG, Clark M, Langenberg P, Scherer R, Frick K, Zhu Q, Hallock L, Nichols J, Yalcinkaya TM; Surgical Treatments Outcomes Project for Dysfunctional Uterine Bleeding (STOP-DUB) Research Group. Hysterectomy compared with endometrial ablation for dysfunctional uterine bleeding: a randomized controlled trial. Obstet Gynecol. 2007;110(6): 1279–1289.
- 139. Gooren LJ, Giltay EJ, Bunck MC. Long-term treatment of transsexuals with cross-sex hormones: extensive personal experience. *J Clin Endocrinol Metab*. 2008;93(1):19–25.
- Prior JC, Vigna YM, Watson D. Spironolactone with physiological female steroids for presurgical therapy of male-to-female transsexualism. *Arch Sex Behav.* 1989;18(1):49–57.
- 141. Dittrich R, Binder H, Cupisti S, Hoffmann I, Beckmann MW, Mueller A. Endocrine treatment of male-to-female transsexuals using gonadotropin-releasing hormone agonist. *Exp Clin Endocrinol Diabetes*. 2005;113(10):586–592.

Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869-3903

- 142. Stripp B, Taylor AA, Bartter FC, Gillette JR, Loriaux DL, Easley R, Menard RH. Effect of spironolactone on sex hormones in man. *J Clin Endocrinol Metab*. 1975;41(4):777–781.
- Levy J, Burshell A, Marbach M, Afllalo L, Glick SM. Interaction of spironolactone with oestradiol receptors in cytosol. *J Endocrinol*. 1980;84(3):371–379.
- 144. Wierckx K, Elaut E, Van Hoorde B, Heylens G, De Cuypere G, Monstrey S, Weyers S, Hoebeke P, T'Sjoen G. Sexual desire in trans persons: associations with sex reassignment treatment. J Sex Med. 2014;11(1):107–118.
- 145. Chiriacò G, Cauci S, Mazzon G, Trombetta C. An observational retrospective evaluation of 79 young men with long-term adverse effects after use of finasteride against androgenetic alopecia. *Andrology*. 2016;4(2):245–250.
- 146. Gava G, Cerpolini S, Martelli V, Battista G, Seracchioli R, Meriggiola MC. Cyproterone acetate vs leuprolide acetate in combination with transdermal oestradiol in transwomen: a comparison of safety and effectiveness. Clin Endocrinol (Oxf). 2016; 85(2):239–246.
- 147. Casper RF, Yen SS. Rapid absorption of micronized estradiol-17 beta following sublingual administration. *Obstet Gynecol.* 1981; 57(1):62–64.
- 148. Price TM, Blauer KL, Hansen M, Stanczyk F, Lobo R, Bates GW. Single-dose pharmacokinetics of sublingual versus oral administration of micronized 17β-estradiol. Obstet Gynecol. 1997;89(3): 340–345.
- 149. Toorians AWFT, Thomassen MCLGD, Zweegman S, Magdeleyns EJP, Tans G, Gooren LJG, Rosing J. Venous thrombosis and changes of hemostatic variables during cross-sex hormone treatment in transsexual people. J Clin Endocrinol Metab. 2003;88(12): 5723–5729.
- 150. Mepham N, Bouman WP, Arcelus J, Hayter M, Wylie KR. People with gender dysphoria who self-prescribe cross-sex hormones: prevalence, sources, and side effects knowledge. *J Sex Med*. 2014; 11(12):2995–3001.
- Richards C, Bouman WP, Seal L, Barker MJ, Nieder TO, T'Sjoen G. Non-binary or genderqueer genders. *Int Rev Psychiatry*. 2016; 28(1):95–102.
- 152. Cosyns M, Van Borsel J, Wierckx K, Dedecker D, Van de Peer F, Daelman T, Laenen S, T'Sjoen G. Voice in female-to-male transsexual persons after long-term androgen therapy. *Laryngoscope*. 2014;124(6):1409–1414.
- 153. Deuster D, Matulat P, Knief A, Zitzmann M, Rosslau K, Szukaj M, am Zehnhoff-Dinnesen A, Schmidt CM. Voice deepening under testosterone treatment in female-to-male gender dysphoric individuals. Eur Arch Otorhinolaryngol. 2016;273(4):959–965.
- 154. Lapauw B, Taes Y, Simoens S, Van Caenegem E, Weyers S, Goemaere S, Toye K, Kaufman J-M, T'Sjoen GG. Body composition, volumetric and areal bone parameters in male-to-female transsexual persons. *Bone*. 2008;43(6):1016–1021.
- 155. Meyer III WJ, Webb A, Stuart CA, Finkelstein JW, Lawrence B, Walker PA. Physical and hormonal evaluation of transsexual patients: a longitudinal study. *Arch Sex Behav*. 1986;15(2): 121–138.
- Asscheman H, Gooren LJ, Assies J, Smits JP, de Slegte R. Prolactin levels and pituitary enlargement in hormone-treated male-tofemale transsexuals. Clin Endocrinol (Oxf). 1988;28(6):583–588.
- 157. Gooren LJ, Harmsen-Louman W, van Kessel H. Follow-up of prolactin levels in long-term oestrogen-treated male-to-female transsexuals with regard to prolactinoma induction. *Clin Endocrinol (Oxf)*. 1985;22(2):201–207.
- 158. Wierckx K, Van Caenegem E, Schreiner T, Haraldsen I, Fisher AD, Toye K, Kaufman JM, T'Sjoen G. Cross-sex hormone therapy in trans persons is safe and effective at short-time follow-up: results from the European network for the investigation of gender incongruence. J Sex Med. 2014;11(8):1999–2011.

- Ott J, Kaufmann U, Bentz EK, Huber JC, Tempfer CB. Incidence of thrombophilia and venous thrombosis in transsexuals under cross-sex hormone therapy. Fertil Steril. 2010;93(4):1267–1272.
- 160. Giltay EJ, Hoogeveen EK, Elbers JMH, Gooren LJG, Asscheman H, Stehouwer CDA. Effects of sex steroids on plasma total homocysteine levels: a study in transsexual males and females. I Clin Endocrinol Metab. 1998;83(2):550–553.
- 161. van Kesteren PJM, Asscheman H, Megens JAJ, Gooren LJG. Mortality and morbidity in transsexual subjects treated with cross-sex hormones. Clin Endocrinol (Oxf). 1997;47(3): 337–343.
- Wierckx K, Gooren L, T'Sjoen G. Clinical review: breast development in trans women receiving cross-sex hormones. *J Sex Med*. 2014;11(5):1240–1247.
- 163. Bird D, Vowles K, Anthony PP. Spontaneous rupture of a liver cell adenoma after long term methyltestosterone: report of a case successfully treated by emergency right hepatic lobectomy. Br J Surg. 1979;66(3):212–213.
- Westaby D, Ogle SJ, Paradinas FJ, Randell JB, Murray-Lyon IM. Liver damage from long-term methyltestosterone. *Lancet*. 1977; 2(8032):262–263.
- 165. Weinand JD, Safer JD. Hormone therapy in transgender adults is safe with provider supervision; a review of hormone therapy sequelae for transgender individuals. *J Clin Transl Endocrinol*. 2015;2(2):55–60.
- 166. Roberts TK, Kraft CS, French D, Ji W, Wu AH, Tangpricha V, Fantz CR. Interpreting laboratory results in transgender patients on hormone therapy. Am J Med. 2014;127(2):159–162.
- Vesper HW, Botelho JC, Wang Y. Challenges and improvements in testosterone and estradiol testing. *Asian J Androl.* 2014;16(2): 178–184.
- 168. Asscheman H, T'Sjoen G, Lemaire A, Mas M, Meriggiola MC, Mueller A, Kuhn A, Dhejne C, Morel-Journel N, Gooren LJ. Venous thrombo-embolism as a complication of cross-sex hormone treatment of male-to-female transsexual subjects: a review. *Andrologia*. 2014;46(7):791–795.
- 169. Righini M, Perrier A, De Moerloose P, Bounameaux H. D-dimer for venous thromboembolism diagnosis: 20 years later. *J Thromb Haemost*. 2008;6(7):1059–1071.
- Gooren LJ, Assies J, Asscheman H, de Slegte R, van Kessel H. Estrogen-induced prolactinoma in a man. J Clin Endocrinol Metab. 1988;66(2):444–446.
- 171. Kovacs K, Stefaneanu L, Ezzat S, Smyth HS. Prolactin-producing pituitary adenoma in a male-to-female transsexual patient with protracted estrogen administration. A morphologic study. *Arch Pathol Lab Med.* 1994;118(5):562–565.
- 172. Serri O, Noiseux D, Robert F, Hardy J. Lactotroph hyperplasia in an estrogen treated male-to-female transsexual patient. *J Clin Endocrinol Metab*. 1996;81(9):3177–3179.
- 173. Cunha FS, Domenice S, Câmara VL, Sircili MH, Gooren LJ, Mendonça BB, Costa EM. Diagnosis of prolactinoma in two maleto-female transsexual subjects following high-dose cross-sex hormone therapy. *Andrologia*. 2015;47(6):680–684.
- 174. Nota NM, Dekker MJHJ, Klaver M, Wiepjes CM, van Trotsenburg MA, Heijboer AC, den Heijer M. Prolactin levels during short- and long-term cross-sex hormone treatment: an observational study in transgender persons. *Andrologia*. 2017;49(6).
- 175. Bunck MC, Debono M, Giltay EJ, Verheijen AT, Diamant M, Gooren LJ. Autonomous prolactin secretion in two male-tofemale transgender patients using conventional oestrogen dosages. BMJ Case Rep. 2009;2009:bcr0220091589.
- 176. Elamin MB, Garcia MZ, Murad MH, Erwin PJ, Montori VM. Effect of sex steroid use on cardiovascular risk in transsexual individuals: a systematic review and meta-analyses. Clin Endocrinol (Oxf). 2010;72(1):1–10.
- 177. Berra M, Armillotta F, D'Emidio L, Costantino A, Martorana G, Pelusi G, Meriggiola MC. Testosterone decreases adiponectin

doi: 10.1210/jc.2017-01658

https://academic.oup.com/jcem

levels in female to male transsexuals. Asian J Androl. 2006;8(6): 725-729.

Document: 78-2

Document: 2-3

Page: 39

Page: 114

- 178. Elbers JMH, Giltay EJ, Teerlink T, Scheffer PG, Asscheman H, Seidell JC, Gooren LJG. Effects of sex steroids on components of the insulin resistance syndrome in transsexual subjects. Clin Endocrinol (Oxf). 2003;58(5):562-571.
- 179. Giltay EJ, Lambert J, Gooren LJG, Elbers JMH, Steyn M, Stehouwer CDA. Sex steroids, insulin, and arterial stiffness in women and men. Hypertension. 1999;34(4 Pt 1):590-597.
- 180. Polderman KH, Gooren LJ, Asscheman H, Bakker A, Heine RJ. Induction of insulin resistance by androgens and estrogens. J Clin Endocrinol Metab. 1994;79(1):265-271.
- 181. Maraka S. Effect of sex steroids on lipids, venous thromboembolism, cardiovascular disease and mortality in transgender individuals: a systematic review and meta-analysis. Available at: http://press. endocrine.org/doi/abs/10.1210/endo-meetings.2016.RE.15.FRI-136. Accessed 3 July 2017.
- 182. Meriggiola MC, Armillotta F, Costantino A, Altieri P, Saad F, Kalhorn T, Perrone AM, Ghi T, Pelusi C, Pelusi G. Effects of testosterone undecanoate administered alone or in combination with letrozole or dutasteride in female to male transsexuals. J Sex Med. 2008;5(10):2442-2453.
- 183. Giltay EJ, Toorians AW, Sarabdjitsingh AR, de Vries NA, Gooren LJ. Established risk factors for coronary heart disease are unrelated to androgen-induced baldness in female-to-male transsexuals. J Endocrinol. 2004;180(1):107-112.
- 184. Giltay EJ, Verhoef P, Gooren LJG, Geleijnse JM, Schouten EG, Stehouwer CDA. Oral and transdermal estrogens both lower plasma total homocysteine in male-to-female transsexuals. Atherosclerosis. 2003;168(1):139-146.
- 185. Calof OM, Singh AB, Lee ML, Kenny AM, Urban RJ, Tenover JL, Bhasin S. Adverse events associated with testosterone replacement in middle-aged and older men: a meta-analysis of randomized, placebo-controlled trials. J Gerontol A Biol Sci Med Sci. 2005; 60(11):1451-1457.
- 186. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA. 2001;285(19):2486-2497.
- 187. Murad MH, Elamin MB, Garcia MZ, Mullan RJ, Murad A, Erwin PJ, Montori VM. Hormonal therapy and sex reassignment: a systematic review and meta-analysis of quality of life and psychosocial outcomes. Clin Endocrinol (Oxf). 2010;72(2): 214-231.
- 188. Van Caenegem E, Wierckx K, Taes Y, Schreiner T, Vandewalle S, Toye K, Lapauw B, Kaufman JM, T'Sjoen G. Body composition, bone turnover, and bone mass in trans men during testosterone treatment: 1-year follow-up data from a prospective casecontrolled study (ENIGI). Eur J Endocrinol. 2015;172(2): 163-171.
- 189. Turner A, Chen TC, Barber TW, Malabanan AO, Holick MF, Tangpricha V. Testosterone increases bone mineral density in female-to-male transsexuals: a case series of 15 subjects. Clin Endocrinol (Oxf). 2004;61(5):560-566.
- 190. van Kesteren P, Lips P, Gooren LJG, Asscheman H, Megens J. Long-term follow-up of bone mineral density and bone metabolism in transsexuals treated with cross-sex hormones. Clin Endocrinol (Oxf). 1998;48(3):347-354.
- 191. Van Caenegem E, Taes Y, Wierckx K, Vandewalle S, Toye K, Kaufman JM, Schreiner T, Haraldsen I, T'Sjoen G. Low bone mass is prevalent in male-to-female transsexual persons before the start of cross-sex hormonal therapy and gonadectomy. Bone. 2013;54(1):92-97.
- 192. Amin S, Zhang Y, Sawin CT, Evans SR, Hannan MT, Kiel DP, Wilson PW, Felson DT. Association of hypogonadism and

- estradiol levels with bone mineral density in elderly men from the Framingham study. Ann Intern Med. 2000;133(12):951-963.
- 193. Gennari L, Khosla S, Bilezikian JP. Estrogen and fracture risk in men. J Bone Miner Res. 2008;23(10):1548-1551.

Filed: 10/31/2024

Filed: 01/25/2024

- 194. Khosla S, Melton LJ III, Atkinson EJ, O'Fallon WM, Klee GG, Riggs BL. Relationship of serum sex steroid levels and bone turnover markers with bone mineral density in men and women: a key role for bioavailable estrogen. J Clin Endocrinol Metab. 1998;83(7):2266-2274.
- 195. Mueller A, Dittrich R, Binder H, Kuehnel W, Maltaris T, Hoffmann I, Beckmann MW. High dose estrogen treatment increases bone mineral density in male-to-female transsexuals receiving gonadotropin-releasing hormone agonist in the absence of testosterone. Eur J Endocrinol. 2005;153(1):107-113.
- 196. Ruetsche AG, Kneubuehl R, Birkhaeuser MH, Lippuner K. Cortical and trabecular bone mineral density in transsexuals after long-term cross-sex hormonal treatment: a cross-sectional study. Osteoporos Int. 2005;16(7):791-798.
- 197. Ganly I, Taylor EW. Breast cancer in a trans-sexual man receiving hormone replacement therapy. Br J Surg. 1995;82(3):341.
- Pritchard TJ, Pankowsky DA, Crowe JP, Abdul-Karim FW. Breast cancer in a male-to-female transsexual. A case report. JAMA. 1988;259(15):2278-2280.
- 199. Symmers WS. Carcinoma of breast in trans-sexual individuals after surgical and hormonal interference with the primary and secondary sex characteristics. BMJ. 1968;2(5597):83-85.
- 200. Brown GR. Breast cancer in transgender veterans: a ten-case series. LGBT Health. 2015;2(1):77-80.
- 201. Shao T, Grossbard ML, Klein P. Breast cancer in female-to-male transsexuals: two cases with a review of physiology and management. Clin Breast Cancer. 2011;11(6):417-419.
- 202. Nikolic DV, Djordjevic ML, Granic M, Nikolic AT, Stanimirovic VV, Zdravkovic D, Jelic S. Importance of revealing a rare case of breast cancer in a female to male transsexual after bilateral mastectomy. World J Surg Oncol. 2012;10:280.
- 203. Bösze P, Tóth A, Török M. Hormone replacement and the risk of breast cancer in Turner's syndrome. N Engl J Med. 2006;355(24):
- 204. Schoemaker MJ, Swerdlow AJ, Higgins CD, Wright AF, Jacobs PA; UK Clinical Cytogenetics Group. Cancer incidence in women with Turner syndrome in Great Britain: a national cohort study. Lancet Oncol. 2008;9(3):239-246.
- 205. Smith RA, Cokkinides V, Eyre HJ. American Cancer Society guidelines for the early detection of cancer, 2006. CA Cancer J Clin. 2006;56(1):11-25, quiz 49-50.
- Wilson JD, Roehrborn C. Long-term consequences of castration in men: lessons from the Skoptzy and the eunuchs of the Chinese and Ottoman courts. J Clin Endocrinol Metab. 1999;84(12): 4324-4331.
- 207. van Kesteren P, Meinhardt W, van der Valk P, Geldof A, Megens J, Gooren L. Effects of estrogens only on the prostates of aging men. I Urol. 1996;156(4):1349-1353.
- 208. Brown JA, Wilson TM. Benign prostatic hyperplasia requiring transurethral resection of the prostate in a 60-year-old male-tofemale transsexual. Br J Urol. 1997;80(6):956-957.
- 209. Casella R, Bubendorf L, Schaefer DJ, Bachmann A, Gasser TC, Sulser T. Does the prostate really need androgens to grow? Transurethral resection of the prostate in a male-to-female transsexual 25 years after sex-changing operation. Urol Int. 2005;75(3):288-290.
- 210. Dorff TB, Shazer RL, Nepomuceno EM, Tucker SJ. Successful treatment of metastatic androgen-independent prostate carcinoma in a transsexual patient. Clin Genitourin Cancer. 2007;5(5): 344-346.
- 211. Thurston AV. Carcinoma of the prostate in a transsexual. Br J Urol. 1994;73(2):217.

2023

3902 Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869-3903

212. van Harst EP, Newling DW, Gooren LJ, Asscheman H, Prenger DM. Metastatic prostatic carcinoma in a male-to-female transsexual. BJU Int. 1998;81:776.

Case: 24-1714

Case: 24-108

- 213. Turo R, Jallad S, Prescott S, Cross WR. Metastatic prostate cancer in transsexual diagnosed after three decades of estrogen therapy. Can Urol Assoc J. 2013;7(7-8):E544-E546.
- 214. Miksad RA, Bubley G, Church P, Sanda M, Rofsky N, Kaplan I, Cooper A. Prostate cancer in a transgender woman 41 years after initiation of feminization. JAMA. 2006;296(19):2316-2317.
- 215. Moyer VA; U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012;157(2):120-134.
- 216. Futterweit W. Endocrine therapy of transsexualism and potential complications of long-term treatment. Arch Sex Behav. 1998; 27(2):209-226.
- 217. Miller N, Bédard YC, Cooter NB, Shaul DL. Histological changes in the genital tract in transsexual women following androgen therapy. Histopathology. 1986;10(7):661-669.
- 218. O'Hanlan KA, Dibble SL, Young-Spint M. Total laparoscopic hysterectomy for female-to-male transsexuals. Obstet Gynecol. 2007;110(5):1096-1101.
- 219. Dizon DS, Tejada-Berges T, Koelliker S, Steinhoff M, Granai CO. Ovarian cancer associated with testosterone supplementation in a female-to-male transsexual patient. Gynecol Obstet Invest. 2006; 62(4):226-228.
- 220. Hage JJ, Dekker JJML, Karim RB, Verheijen RHM, Bloemena E. Ovarian cancer in female-to-male transsexuals: report of two cases. Gynecol Oncol. 2000;76(3):413-415.
- 221. Mueller A, Gooren L. Hormone-related tumors in transsexuals receiving treatment with cross-sex hormones. Eur J Endocrinol. 2008;159(3):197–202.
- 222. Coleman E, Bockting W, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J, Fraser L, Green J, Knudson G, Meyer WJ, Monstrey S, Adler RK, Brown GR, Devor AH, Ehrbar R, Ettner R, Eyler E, Garofalo R, Karasic DH, Lev AI, Mayer G, Meyer-Bahlburg H, Hall BP, Pfaefflin F, Rachlin K, Robinson B, Schechter LS, Tangpricha V, van Trotsenburg M, Vitale A, Winter S, Whittle S, Wylie KR, Zucker K. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. Int J Transgenderism. 2012;13:165-232.
- 223. Colebunders B, D'Arpa S, Weijers S, Lumen N, Hoebeke P, Monstrey S. Female-to-male gender reassignment surgery. In: Ettner R, Monstrey S, Coleman E, eds. Principles of Transgender Medicine and Surgery. 2nd ed. New York, NY: Routledge Taylor & Francis Group; 2016:279-317.
- 224. Monstrey S, Hoebeke P, Dhont M, De Cuypere G, Rubens R, Moerman M, Hamdi M, Van Landuyt K, Blondeel P. Surgical therapy in transsexual patients: a multi-disciplinary approach. Acta Chir Belg. 2001;101(5):200-209.
- 225. Selvaggi G, Ceulemans P, De Cuypere G, VanLanduyt K, Blondeel P, Hamdi M, Bowman C, Monstrey S. Gender identity disorder: general overview and surgical treatment for vaginoplasty in male-to-female transsexuals. Plast Reconstr Surg. 2005;116(6):
- 226. Tugnet N, Goddard JC, Vickery RM, Khoosal D, Terry TR. Current management of male-to-female gender identity disorder in the UK. Postgrad Med J. 2007;83(984):638-642.
- 227. Horbach SER, Bouman M-B, Smit JM, Özer M, Buncamper ME, Mullender MG. Outcome of vaginoplasty in male-to-female transgenders: a systematic review of surgical techniques. J Sex Med. 2015;12(6):1499-1512.
- 228. Wroblewski P, Gustafsson J, Selvaggi G. Sex reassignment surgery for transsexuals. Curr Opin Endocrinol Diabetes Obes. 2013; 20(6):570-574.
- 229. Morrison SD, Satterwhite T, Grant DW, Kirby J, Laub DR, Sr, VanMaasdam J. Long-term outcomes of rectosigmoid neocolporrhaphy in male-to-female gender reassignment surgery. Plast Reconstr Surg. 2015;136(2):386-394.

- 230. Dessy LA, Mazzocchi M, Corrias F, Ceccarelli S, Marchese C, Scuderi N. The use of cultured autologous oral epithelial cells for vaginoplasty in male-to-female transsexuals: a feasibility, safety, and advantageousness clinical pilot study. Plast Reconstr Surg. 2014:133(1):158-161.
- 231. Li FY, Xu YS, Zhou CD, Zhou Y, Li SK, Li Q. Long-term outcomes of vaginoplasty with autologous buccal micromucosa. Obstet Gynecol. 2014;123(5):951-956.
- 232. Kanhai RC. Sensate vagina pedicled-spot for male-to-female transsexuals: the experience in the first 50 patients. Aesthetic Plast Surg. 2016;40(2):284-287.
- 233. Straayer C. Transplants for transsexuals? Ambitions, concerns, ideology. Paper presented at: Trans*Studies: An International Transdisciplinary Conference on Gender, Embodiment, and Sexuality; 7-10 September 2016; University of Arizona, Tucson,
- 234. Bucci S, Mazzon G, Liguori G, Napoli R, Pavan N, Bormioli S, Ollandini G, De Concilio B, Trombetta C. Neovaginal prolapse in male-to-female transsexuals: an 18-year-long experience. Biomed Res Int. 2014;2014:240761.
- 235. Raigosa M, Avvedimento S, Yoon TS, Cruz-Gimeno J, Rodriguez G, Fontdevila J. Male-to-female genital reassignment surgery: a retrospective review of surgical technique and complications in 60 patients. J Sex Med. 2015;12(8):1837-1845.
- 236. Green R. Sexual functioning in post-operative transsexuals: maleto-female and female-to-male. Int J Impot Res. 1998;10(Suppl 1): S22-S24.
- 237. Hess J, Rossi Neto R, Panic L, Rübben H, Senf W. Satisfaction with male-to-female gender reassignment surgery. Dtsch Arztebl Int. 2014;111(47):795-801.
- 238. Nygren U, Nordenskjold A, Arver S, Sodersten M. Effects on voice fundamental frequency and satisfaction with voice in trans men during testosterone treatment—a longitudinal study. J Voice. 2016;30(6):766.e23-766.e34.
- 239. Becking AG, Tuinzing DB, Hage JJ, Gooren LJG. Transgender feminization of the facial skeleton. Clin Plast Surg. 2007;34(3): 557-564.
- 240. Giraldo F, Esteva I, Bergero T, Cano G, González C, Salinas P, Rivada E, Lara JS, Soriguer F; Andalusia Gender Team. Corona glans clitoroplasty and urethropreputial vestibuloplasty in maleto-female transsexuals: the vulval aesthetic refinement by the Andalusia Gender Team. Plast Reconstr Surg. 2004;114(6): 1543-1550.
- 241. Goddard JC, Vickery RM, Terry TR. Development of feminizing genitoplasty for gender dysphoria. J Sex Med. 2007;4(4 Pt 1):
- 242. Hage JJ, de Graaf FH, Bouman FG, Bloem JJAM. Sculpturing the glans in phalloplasty. Plast Reconstr Surg. 1993;92(1):157-161, discussion 162.
- 243. Thiagaraj D, Gunasegaram R, Loganath A, Peh KL, Kottegoda SR, Ratnam SS. Histopathology of the testes from male transsexuals on oestrogen therapy. Ann Acad Med Singapore. 1987; 16(2):347-348.
- 244. Monstrey SJ, Ceulemans P, Hoebeke P. Sex reassignment surgery in the female-to-male transsexual. Semin Plast Surg. 2011;25(3):
- 245. Perovic SV, Djinovic R, Bumbasirevic M, Djordjevic M, Vukovic P. Total phalloplasty using a musculocutaneous latissimus dorsi flap. BJU Int. 2007;100(4):899-905, discussion 905.
- 246. Vesely J, Hyza P, Ranno R, Cigna E, Monni N, Stupka I, Justan I, Dvorak Z, Novak P, Ranno S. New technique of total phalloplasty with reinnervated latissimus dorsi myocutaneous free flap in female-to-male transsexuals. Ann Plast Surg. 2007;58(5): 544-550.
- 247. Ranno R, Veselý J, Hýza P, Stupka I, Justan I, Dvorák Z, Monni N, Novák P, Ranno S. Neo-phalloplasty with re-innervated latissimus dorsi free flap: a functional study of a novel technique. Acta Chir Plast. 2007;49(1):3-7.

doi: 10.1210/jc.2017-01658

https://academic.oup.com/jcem

248. Garcia MM, Christopher NA, De Luca F, Spilotros M, Ralph DJ. Overall satisfaction, sexual function, and the durability of neophallus dimensions following staged female to male genital gender confirming surgery: the Institute of Urology, London U.K. experience. Transl Androl Urol. 2014;3(2):156-162.

- 249. Chen H-C, Gedebou TM, Yazar S, Tang Y-B. Prefabrication of the free fibula osteocutaneous flap to create a functional human penis using a controlled fistula method. J Reconstr Microsurg. 2007; 23(3):151-154.
- 250. Hoebeke PB, Decaestecker K, Beysens M, Opdenakker Y, Lumen N, Monstrey SM. Erectile implants in female-to-male transsexuals: our experience in 129 patients. Eur Urol. 2010;57(2): 334-341.
- 251. Hage JJ. Metaidoioplasty: an alternative phalloplasty technique in transsexuals. Plast Reconstr Surg. 1996;97(1):161-167.
- 252. Cohanzad S. Extensive metoidioplasty as a technique capable of creating a compatible analogue to a natural penis in female transsexuals. Aesthetic Plast Surg. 2016;40(1):130-138.
- 253. Selvaggi G, Hoebeke P, Ceulemans P, Hamdi M, Van Landuvt K, Blondeel P, De Cuypere G, Monstrey S. Scrotal reconstruction in female-to-male transsexuals: a novel scrotoplasty. Plast Reconstr Surg. 2009;123(6):1710-1718.
- 254. Bjerrome Ahlin H, Kölby L, Elander A, Selvaggi G. Improved results after implementation of the Ghent algorithm for subcutaneous mastectomy in female-to-male transsexuals. I Plast Surg Hand Surg. 2014;48(6):362-367.
- 255. Wolter A, Diedrichson J, Scholz T, Arens-Landwehr A, Liebau J. Sexual reassignment surgery in female-to-male transsexuals: an algorithm for subcutaneous mastectomy. I Plast Reconstr Aesthet Surg. 2015;68(2):184-191.
- 256. Richards C, Barrett J. The case for bilateral mastectomy and male chest contouring for the female-to-male transsexual. Ann R Coll Surg Engl. 2013;95(2):93-95.
- 257. Sutcliffe PA, Dixon S, Akehurst RL, Wilkinson A, Shippam A, White S, Richards R, Caddy CM. Evaluation of surgical

- procedures for sex reassignment: a systematic review. J Plast Reconstr Aesthet Surg. 2009;62(3):294–306, discussion 306–308.
- 258. Selvaggi G, Elander A. Penile reconstruction/formation. Curr Opin Urol. 2008;18(6):589-597.

Filed: 10/31/2024

Filed: 01/25/2024

Page: 41

Page: 116

- 259. Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One. 2011:6(2):e16885.
- 260. Kuhn A, Bodmer C, Stadlmayr W, Kuhn P, Mueller MD, Birkhäuser M. Quality of life 15 years after sex reassignment surgery for transsexualism. Fertil Steril. 2009;92(5):1685–1689.e3.
- 261. Papadopulos NA, Lellé JD, Zavlin D, Herschbach P, Henrich G, Kovacs L, Ehrenberger B, Kluger AK, Machens HG, Schaff J. Quality of life and patient satisfaction following male-to-female sex reassignment surgery. J Sex Med. 2017;14(5):721-730.
- 262. Simonsen RK, Hald GM, Kristensen E, Giraldi A. Long-term follow-up of individuals undergoing sex-reassignment surgery: somatic morbidity and cause of death. Sex Med. 2016;4(1): e60-e68.
- 263. Djordjevic ML, Bizic MR, Duisin D, Bouman MB, Buncamper M. Reversal Surgery in regretful male-to-female transsexuals after sex reassignment surgery. J Sex Med. 2016;13(6):1000-1007.
- 264. Liberopoulos EN, Florentin M, Mikhailidis DP, Elisaf MS. Compliance with lipid-lowering therapy and its impact on cardiovascular morbidity and mortality. Expert Opin Drug Saf. 2008;7(6):717-725.
- 265. Forbes SS, Stephen WJ, Harper WL, Loeb M, Smith R, Christoffersen EP, McLean RF. Implementation of evidence-based practices for surgical site infection prophylaxis: results of a preand postintervention study. J Am Coll Surg. 2008;207(3): 336-341.
- 266. Davis PJ, Spady D, de Gara C, Forgie SE. Practices and attitudes of surgeons toward the prevention of surgical site infections: a provincial survey in Alberta, Canada. Infect Control Hosp Epidemiol. 2008;29(12):1164–1166.

Case: 24-1714 Document: 78-2 Page: 42 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 171 Filed: 01/25/2024

DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS

FIFTH EDITION
TEXT REVISION

DSM-5-TR™





Case: 24-1714 Document: 78-2 Page: 43 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 172 Filed: 01/25/2024

RC435.2 .C4 A48 2022

Copyright © 2022 American Psychiatric Association

DSM, DSM-5, and DSM-5-TR are registered trademarks of the American Psychiatric Association. Use of these terms is prohibited without permission of the American Psychiatric Association.

ALL RIGHTS RESERVED. Unless authorized in writing by the APA, no part of this book may be reproduced or used in a manner inconsistent with the APA's copyright. This prohibition applies to unauthorized uses or reproductions in any form, including electronic applications.

Correspondence regarding copyright permissions should be directed to DSM Permissions, American Psychiatric Association Publishing, 800 Maine Avenue SW, Suite 900, Washington, DC 20024-2812.

Manufactured in the United States of America on acid-free paper.

ISBN 978-0-89042-575-6 (Hardcover) 1st printing February 2022

ISBN 978-0-89042-576-3 (Paperback) 1st printing February 2022

American Psychiatric Association 800 Maine Avenue SW Suite 900 Washington, DC 20024-2812

The correct citation for this book is American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2022.

Library of Congress Cataloging-in-Publication Data

Names: American Psychiatric Association, issuing body.

Title: Diagnostic and statistical manual of mental disorders: DSM-5-TR / American Psychiatric Association.

Other titles: DSM-5-TR

www.psychiatry.org

Description: Fifth edition, text revision. | Washington, DC: American Psychiatric Association Publishing, [2022] | Includes index.

Identifiers: LCCN 2021051781 (print) | LCCN 2021051782 (ebook) | ISBN 9780890425756 (hardcover; alk. paper) | ISBN 9780890425763 (paperback; alk. paper) | ISBN 9780890425770 (ebook)

Subjects: MESH: Diagnostic and statistical manual of mental disorders. 5th ed | Mental Disorders—classification | Mental Disorders—diagnosis

Classification: LCC RC455.2.C4 (print) | LCC RC455.2.C4 (ebook) | NLM WM 15 | DDC 616.89/ 075—dc23/eng/20211209

LC record available at https://lccn.loc.gov/2021051781

LC ebook record available at https://lccn.loc.gov/2021051782.

British Library Cataloguing in Publication Data

A CIP record is available from the British Library.

Text Design—Tammy J. Cordova

Manufacturing—Sheridan Books, Inc.

EASTERN WASHINGTON UNIVERSITY LIBRARIES CHENEY, WA 99004

Appx418

Case: 24-1714 Document: 78-2 Page: 44 Filed: 10/31/2024 Case: 24-108 Filed: 01/25/2024 Document: 2-3 Page: 173

Gender **Dysphoria**

In this chapter, there is one overarching diagnosis of gender dysphoria, with separate developmentally appropriate criteria sets for children and for adolescents and adults. The area of sex and gender is highly controversial and has led to a proliferation of terms whose meanings vary over time and within and between disciplines. An additional source of confusion is that in English "sex" connotes both male/female and sexuality. This chapter employs constructs and terms as they are widely used by clinicians from various disciplines with specialization in treating gender dysphoria. In this chapter, sex and sexual refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia. Disorders of sex development or differences of sex development (DSDs) included the historical terms hermaphroditism and pseudohermaphroditism. DSDs include somatic intersex conditions such as congenital development of ambiguous genitalia (e.g., clitoromegaly, micropenis), congenital disjunction of internal and external sex anatomy (e.g., complete androgen insensitivity syndrome), incomplete development of sex anatomy (e.g., gonadal agenesis), sex chromosome anomalies (e.g., Turner syndrome; Klinefelter syndrome), or disorders of gonadal development (e.g., ovotestes).

Gender is used to denote the public, sociocultural (and usually legally recognized) lived role as boy or girl, man or woman, or other gender. Biological factors are seen as contributing, in interaction with social and psychological factors, to gender development. Gender assignment refers to the assignment as male or female. This occurs usually at birth based on phenotypic sex and, thereby, yields the birth-assigned gender, historically referred to as "biological sex" or, more recently, "natal gender." Birth-assigned sex is often used interchangeably with birth-assigned gender. The terms assigned sex and assigned gender encompass birth-assigned sex/gender but also include gender/sex assignments and reassignments made after birth but during infancy or early childhood, usually in the case of intersex conditions. Gender-atypical refers to somatic features or behaviors that are not typical (in a statistical sense) of individuals with the same assigned gender in a given society and historical era; gender-nonconforming, gender variant, and gender diverse are alternative nondiagnostic terms. Gender reassignment denotes an official (and sometimes legal) change of gender. Gender-affirming treatments are medical procedures (hormones or surgeries or both) that aim to align an individual's physical characteristics with their experienced gender. Gender identity is a category of social identity and refers to an individual's identification as male, female, some category in between (i.e., gender fluid), or a category other than male or female (i.e., gender neutral). There has been a proliferation of gender identities in recent years. Gender dysphoria as a general descriptive term refers to the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender. However, it is more specifically defined when used as a diagnostic category. It does not refer to distress related to stigma, a distinct although possibly co-occurring source of distress. Transgender refers to the broad spectrum of individuals whose gender identity is different from their birth-assigned gender. Cisgender describes individuals whose gender expression is congruent with their birth-assigned gender (also nontransgender). Transsexual, a historic term, denotes an individual who seeks, is undergoing,

Case: 24-1714 Document: 78-2 Page: 45 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 174 Filed: 01/25/2024

512 Gender Dysphoria

or has undergone a social transition from male to female or female to male, which in many, but not all, cases also involves a somatic transition by gender-affirming hormone treatment and genital, breast, or other gender-affirming surgery (historically referred to as sex reassignment surgery).

Although not all individuals will experience distress from incongruence, many are distressed if the desired physical interventions using hormones and/or surgery are not available. The current term is more descriptive than the previous DSM-IV term *gender identity disorder* and focuses on dysphoria as the clinical problem, not identity per se.

Gender Dysphoria

Diagnostic Criteria

Gender Dysphoria in Children

64.2

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):
 - 1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
 - In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
 - 3. A strong preference for cross-gender roles in make-believe play or fantasy play.
 - 4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
 - 5. A strong preference for playmates of the other gender.
 - In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
 - 7. A strong dislike of one's sexual anatomy.
 - A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
- B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Specify if:

With a disorder/difference of sex development (e.g., a congenital adrenogenital disorder such as E25.0 congenital adrenal hyperplasia or E34.50 androgen insensitivity syndrome).

Coding note: Code the disorder/difference of sex development as well as gender dysphoria.

Gender Dysphoria in Adolescents and Adults

F64.0

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
 - A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).

Case: 24-1714 Document: 78-2 Page: 46 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 175 Filed: 01/25/2024

Gender Dysphoria 513

A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).

- A strong desire for the primary and/or secondary sex characteristics of the other gender.
- A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
- A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
- A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:

With a disorder/difference of sex development (e.g., a congenital adrenogenital disorder such as E25.0 congenital adrenal hyperplasia or E34.50 androgen insensitivity syndrome).

Coding note: Code the disorder/difference of sex development as well as gender dysphoria.

Specify if:

Posttransition: The individual has transitioned to full-time living in the experienced gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one gender-affirming medical procedure or treatment regimen—namely, regular gender-affirming hormone treatment or gender reassignment surgery confirming the experienced gender (e.g., breast augmentation surgery and/or vulvovaginoplasty in an individual assigned male at birth; transmasculine chest surgery and/or phalloplasty or metoidioplasty in an individual assigned female at birth).

Specifiers

The specifier "with a disorder/difference of sex development" should be used in the context of individuals who have a specific and codable disorder/difference of sex development documented in their medical record.

The "posttransition" specifier may be used in the context of continuing treatment procedures that serve to support the new gender assignment.

Diagnostic Features

Individuals with gender dysphoria have a marked incongruence between the gender to which they have been assigned (usually based on phenotypic sex at birth, referred to as birth-assigned gender) and their experienced/expressed gender. This discrepancy is the core component of the diagnosis. There must also be evidence of distress about this incongruence. Experienced gender may include alternative gender identities beyond binary stereotypes. Consequently, distress may involve not only the experience that the individual is a male or female gender other than the one assigned at birth but also an experience that the individual is an intermediate or alternative gender that differs from the individual's birth-assigned gender.

Gender dysphoria manifests itself differently in different age groups. The following examples may be less prominent in children raised in surroundings with fewer gender stereotypes.

Prepubertal individuals assigned female at birth with gender dysphoria may express a marked, persistent feeling or conviction that they are a boy, express aversion to the idea of

Case: 24-1714 Document: 78-2 Page: 47 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 176 Filed: 01/25/2024

514 Gender Dysphoria

being a girl, or assert they will grow up to be a man. They often prefer boys' clothing and hairstyles, may be perceived by strangers as boys, and may ask to be called by a boy's name. Sometimes they display intense negative reactions to parental attempts to have them wear dresses or other feminine attire. Some may refuse to attend school or social events where such clothes are required. These children may demonstrate marked gender nonconformity in role-playing, dreams, gender-typed play and toy preferences, styles, mannerisms, fantasies, and peer preferences. Contact sports, rough-and-tumble play, traditional boyhood games, and boys as playmates are most often preferred. They show little interest in stereotypically feminine toys (e.g., dolls) or activities (e.g., feminine dress-up or role-play). Occasionally, they refuse to urinate in a sitting position. Some may express a desire to have a penis or claim to have a penis or that they will grow one when older. They may also state that they do not want to develop breasts or menstruate.

Prepubertal individuals assigned male at birth with gender dysphoria may express a marked, persistent feeling or conviction that they are a girl or assert that they will grow up to be a woman. They may express aversion to the idea of being a boy. They often prefer dressing in girls' or women's clothes or may improvise clothing from available materials (e.g., using towels, aprons, and scarves for long hair or skirts). These children may demonstrate marked gender nonconformity in gender-typed play and toy preferences, styles, mannerisms, and peer preferences. They may role-play female figures (e.g., playing "mother") and may be intensely interested in female fantasy figures. Traditional feminine activities, stereotypical games, and pastimes (e.g., "playing house"; drawing feminine pictures; watching television or videos of favorite female characters) may be preferred. Stereotypical female-type dolls (e.g., Barbie) may be favorite toys, and girls are their preferred playmates. They avoid rough-and-tumble play and have little interest in stereotypically masculine toys (e.g., cars, trucks). They may state that they find their penis or testes disgusting, that they wish them removed, or that they have, or wish to have, a vagina.

Increasingly, parents are presenting to specialized clinics after their child with gender

dysphoria has already socially transitioned.

As the onset of puberty for individuals assigned female at birth is somewhere between ages 9 and 13, and between 11 and 14 for individuals assigned male at birth, their symptoms and concerns may arise in a developmental phase somewhere between childhood and adolescence. As secondary sex characteristics of younger adolescents are not yet fully developed, these individuals may not state dislike of them, but they may be markedly dis-

tressed by imminent physical changes.

In adolescents and adults with gender dysphoria, the discrepancy between experienced gender and physical sex characteristics is often, but not always, accompanied by a desire to be rid of primary and/or secondary sex characteristics and/or a strong desire to acquire some primary and/or secondary sex characteristics of another gender. To varying degrees, older adolescents and adults with gender dysphoria may adopt the behavior, clothing, and mannerisms of their experienced gender. They feel uncomfortable being regarded by others, or functioning in society, as members of their assigned gender. Some adults and adolescents may have a strong desire to be of a different gender and treated as such, and they may have an inner certainty to feel and respond as their experienced gender without seeking medical treatment to alter body characteristics. They may find other ways to resolve the incongruence between experienced/expressed and assigned gender by partially living in the desired role or by adopting a gender role neither conventionally male nor conventionally female.

Associated Features

When visible signs of puberty develop, individuals assigned male at birth may shave their facial, body, and leg hair at the first signs of growth. They sometimes bind their genitals to make erections less visible. Individuals assigned female at birth may bind their breasts,

Case: 24-1714 Document: 78-2 Page: 48 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 177 Filed: 01/25/2024

Gender Dysphoria 515

walk with a stoop, or use loose sweaters to make breasts less visible. Increasingly, adolescents request, or may obtain without medical prescription and supervision, drugs that suppress production of gonadal steroids (e.g., gonadotropin-releasing hormone [GnRH] agonists) or that block gonadal hormone actions (e.g., spironolactone). Clinically referred adolescents often want hormone treatment and many also wish for gender-affirming surgery. Adolescents living in an accepting environment may openly express the desire to be and be treated as their experienced gender and dress partly or completely as their experienced gender, have a hairstyle typical of their experienced gender, preferentially seek friendships with peers of another gender, and/or adopt a new first name consistent with their experienced gender. Older adolescents, when sexually active, often do not show or allow partners to touch their sexual organs. For adults with an aversion toward their genitals, sexual activity is constrained by the preference that their genitals not be seen or touched by their partners. Not infrequently, adults may seek hormone treatment (sometimes without medical prescription and supervision) and gender-affirming surgery. Others are satisfied with either hormone treatment or surgery alone, or without any gender-affirming medical treatment.

In children, adolescents, and adults with gender dysphoria, an overrepresentation of autism spectrum traits has been observed. Also, individuals with autism spectrum disorder are more likely to exhibit gender diversity.

Adolescents and adults with gender dysphoria before gender-affirming treatment and legal gender change are at increased risk for mental health problems including suicidal ideation, suicide attempts, and suicides. After gender reassignment, adjustment may vary, and suicide risk and mental health problems may persist.

In prepubertal children, increasing age is associated with having more behavioral or emotional problems; this is related to the increasing nonacceptance of gender-nonconforming behavior by others. Children and adolescents who feel supported and accepted in their gender nonconformity may show less or even no psychological problems.

Prevalence

There are no large-scale population studies of gender dysphoria. Based on gender-affirming treatment–seeking populations, the prevalence for gender dysphoria diagnosis across populations has been assessed to be less than 1/1,000 (i.e., <0.1%) for both individuals assigned male at birth and individuals assigned female at birth. Because many adults with gender dysphoria do not seek care at specialty treatment programs, prevalence rates are likely underestimates. Prevalence estimates based on surveys of self-reporting general population samples in the United States and Europe suggest higher numbers, although varied methods of assessment make comparisons difficult across studies. Self-identification as transgender ranges from 0.5% to 0.6%; experiencing oneself as having an incongruent gender identity ranges from 0.6% to 1.1%; feeling that one is a person of a different sex ranges from 2.1% to 2.6%; and the desire to undergo medical treatment ranges from 0.2% to 0.6%.

Development and Course

Because expression of gender dysphoria varies with age, there are separate criteria sets for children versus those for adolescents and adults. Criteria for children are defined in a more concrete, behavioral manner than those for adolescents and adults. Young children are less likely than older children, adolescents, and adults to express extreme and persistent anatomic dysphoria. In adolescents and adults, incongruence between experienced gender and assigned gender is a central feature of the diagnosis. Factors related to distress and impairment also vary with age. A very young child may show signs of distress (e.g., intense crying) only when parents tell the child that he or she is "really" not a member of another gender but only "desires" to be. Distress may not be manifest in social environments supportive of the child's gender nonconformity and may emerge only if there is parental/

Case: 24-1714 Document: 78-2 Page: 49 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 178 Filed: 01/25/2024

516 Gender Dysphoria

social interference with the child's gender variance. In adolescents and adults, distress may manifest because of strong incongruence between experienced gender and birth-assigned gender. Such distress may, however, be mitigated by supportive environments and knowledge that biomedical treatments exist to reduce incongruence. Impairment (e.g., school refusal, development of depression, anxiety, peer and behavioral problems, and substance abuse) may be a correlate of gender dysphoria.

Gender dysphoria without a disorder of sex development. For clinic-referred children studied in Canada and the Netherlands, onset of gender-nonconforming behaviors is usually between ages 2 and 4 years. This corresponds to the developmental time period in which most children begin expressing gendered behaviors and interests. For some preschool-age children, both marked, persistent gender-atypical behaviors and the expressed desire to be another gender may be present, or labeling themselves as a member of another gender may occur. In other cases, the gender expression appears later, usually at entry into elementary school. Children may sometimes express discomfort with their sexual anatomy or will state the desire to have a sexual anatomy corresponding to their experienced gender ("anatomic dysphoria"). Expressions of anatomic dysphoria become more common as children with gender dysphoria approach and anticipate puberty.

No general population studies exist of adolescent or adult outcomes of childhood gender variance. Some prepubescent children expressing a desire to be another gender will not seek gender-affirming somatic treatments when they reach puberty. They frequently report nonheterosexual orientations and frequently marked gender-nonconforming behavior, although not necessarily a transgender identity in adolescence/young adulthood. Some children with gender dysphoria in childhood that remits in adolescence may experience a recurrence in adulthood.

In individuals assigned male at birth, studies from North America and the Netherlands found persistence ranged from 2% to 39%. In individuals assigned female at birth, persistence ranged from 12% to 50%. Persistence of gender dysphoria is modestly correlated with dimensional measures of severity ascertained at the time of a childhood baseline assessment. Early social transition may also be a factor in persistence of gender dysphoria in adolescence.

Studies have shown a high incidence of sexual attraction to those of the individual's birth-assigned gender, regardless of the trajectory of the prepubescent child's gender dysphoria. For individuals whose gender dysphoria continues into adolescence and beyond, most self-identify as heterosexual. In those who no longer have gender dysphoria by the time of adolescence, a majority self-identify as gay, lesbian, or bisexual.

Two broad trajectories have been described for development of gender dysphoria in individuals who identify as either male or female.

As opposed to gender-nonconforming children, individuals with prepubertal-onset gender dysphoria have symptoms that meet diagnostic criteria for gender dysphoria in childhood. The dysphoria can continue into adolescence and adulthood; alternatively, some individuals go through a period in which the gender dysphoria either desists or is denied. At such times, these individuals may self-identify as being gay or lesbian. Some may identify as heterosexual and cisgender. However, it is possible that some of these individuals may experience a recurrence of gender dysphoria later in life.

Regardless of whether the individual's gender dysphoria persists or desists at a later date, either the onset of puberty or the realization that puberty will begin with development of secondary sex characteristics can prompt distressing feelings of gender incongruence that can exacerbate the individual's gender dysphoria.

The early/prepubertal-onset group often present for clinical, gender-affirming care during childhood, during adolescence, or in young adulthood. This may reflect a more intense gender dysphoria compared with individuals with late/postpubertal-onset gender dysphoria, whose distress may be more variable and less intense.

Case: 24-1714 Document: 78-2 Page: 50 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 179 Filed: 01/25/2024

Gender Dysphoria

517

Late-onset or pubertal/postpubertal-onset gender dysphoria occurs around puberty or even much later in life. Some of these individuals report having had a desire to be of another gender in childhood that was not expressed verbally to others or had gender-nonconforming behavior that did not meet full criteria for gender dysphoria in childhood. Others have no recollection of any signs of childhood gender dysphoria. Parents of individuals with gender dysphoria of pubertal/postpubertal-onset often report surprise, as they saw no signs of gender dysphoria during childhood.

Gender dysphoria in association with a disorder of sex development. Individuals with DSDs who require early medical intervention or decisions about gender assignment come to clinical attention at an early age. Depending on the condition, they may have been gonadectomized (often because of risk of future malignancy) before puberty so that administration of exogenous hormones is part of routine care to induce puberty. Infertility is common whether due to the condition itself or to gonadectomy, and genital surgery may have been done in infancy or childhood with the intent of affirming the assigned gender to both the affected individual and caregivers.

Affected individuals may exhibit gender-nonconforming behavior starting in early childhood in a manner that is predictable depending on the specific DSD syndrome and the gender assignment, and thresholds for supporting social and medical gender transition in minors have traditionally been much lower for those with compared to those without DSDs. As individuals with some DSD syndromes become aware of their condition and medical history, many experience uncertainty about their gender, as opposed to developing a firm conviction that they are of another gender. The proportion who develop gender dysphoria and progress to gender transition varies markedly depending on the particular syndrome and gender assignment.

Risk and Prognostic Factors

Temperamental. Gender-variant behavior among individuals with prepubertal-onset gender dysphoria can develop in early preschool age. Studies suggest that a greater intensity of gender nonconformity and an older age at presentation make persistence of gender dysphoria into adolescence and adulthood more likely. A predisposing factor under consideration, especially in individuals with postpubertal-onset gender dysphoria (adolescence, adulthood), includes history of transvestism that may develop into autogynephilia (i.e., sexual arousal associated with the thought or image of oneself as a woman).

Environmental. Individuals assigned male at birth with gender dysphoria without a DSD (in both childhood and adolescence) more commonly have older brothers when compared with cisgender males.

Genetic and physiological. For individuals with gender dysphoria without a DSD, some genetic contribution is suggested by evidence for (weak) familiality of gender dysphoria among nontwin siblings, increased concordance for gender dysphoria in monozygotic compared with dizygotic same-sex twins, and some degree of heritability of gender dysphoria. Research suggests that gender dysphoria has a polygenetic basis involving interactions of several genes and polymorphisms that may affect in utero sexual differentiation of the brain, contributing to gender dysphoria in individuals assigned male at birth.

As to endocrine findings in individuals with gender dysphoria, no endogenous systemic abnormalities in sex-hormone levels have been found in 46,XY individuals, whereas there appear to be increased androgen levels (in the range found in hirsute women but far below normal male levels) in 46,XX individuals. Overall, current evidence is insufficient to label gender dysphoria without a DSD as a form of intersexuality limited to the central nervous system.

In gender dysphoria associated with a DSD, the likelihood of later gender dysphoria is increased if prenatal production and utilization (via receptor sensitivity) of androgens are grossly variant relative to what is usually seen in individuals with the same assigned gen-

Case: 24-1714 Document: 78-2 Page: 51 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 180 Filed: 01/25/2024

518 Gender Dysphoria

der. Examples include 46,XY individuals with a history of normal male prenatal hormone milieu but inborn nonhormonal genital defects (as in cloacal bladder exstrophy or penile agenesis) and who have been assigned to the female gender. The likelihood of gender dysphoria is further enhanced by additional, prolonged, highly gender-variant postnatal androgen exposure with somatic virilization as may occur in female-raised and noncastrated 46,XY individuals with 5-alpha reductase-2 deficiency or 17-beta-hydroxysteroid dehydrogenase-3 deficiency or in female-raised 46,XX individuals with classical congenital adrenal hyperplasia with prolonged periods of nonadherence to glucocorticoid replacement therapy. However, the prenatal androgen milieu is more closely related to gendered behavior than to gender identity. Many individuals with DSDs and markedly gender-variant behavior do not develop gender dysphoria. Thus, gender-nonconforming behavior by itself should not be interpreted as an indicator of current or future gender dysphoria. There appears to be a higher rate of gender dysphoria and patient-initiated gender change from assigned female to male than from assigned male to female in individuals prenatally exposed to a full complement of masculinizing hormonal influences.

Culture-Related Diagnostic Issues

Individuals with gender dysphoria have been reported across many countries and cultural contexts around the world. The equivalent of gender dysphoria has also been reported in individuals living in cultural contexts with institutionalized gender identity categories other than men/boys or women/girls that sanction gender nonconforming development. These include India, Sri Lanka, Myanmar, Oman, Samoa, Thailand, and Indigenous Peoples of North America. It is unclear however, in such cultural contexts, whether the diagnostic criteria for gender dysphoria would be met with these individuals.

The prevalence of coexisting mental health problems differs among cultures; these differences may also be related to differences in attitudes toward gender nonconformity in children, adolescents, and adults. However, also in some non-Western cultures, anxiety has been found to be relatively common in individuals with gender dysphoria, even in cultures with accepting attitudes toward gender-variant behavior.

Sex- and Gender-Related Diagnostic Issues

Sex differences in rate of referrals to specialty clinics vary by age group. In children, sex ratios of individuals assigned male at birth to individuals assigned female at birth range from 1.25:1 to 4.3:1. Studies show increasing numbers of children and adolescents presenting to specialty clinics, presentation at younger ages, more frequent early social transition, and a shift to a greater number of individuals assigned female at birth in adolescents and young adults than individuals assigned male at birth. In adults, estimates generally suggest more individuals assigned male at birth seek gender-affirming treatment, with ratios ranging from 1:1 to 6.1:1 in most studies in the United States and Europe.

Association With Suicidal Thoughts or Behavior

Rates of suicidality and suicide attempts for transgender individuals are reported to range from 30% to 80%, with risk factors including past maltreatment, gender victimization, depression, substance abuse, and younger age. Transgender adolescents referred to gender clinics have substantially higher rates of suicidal thoughts and behaviors when compared with nonreferred adolescents. Prior to receiving gender-affirming treatment and legal gender reassignment, adolescents and adults with gender dysphoria are at increased risk for suicidal thoughts and suicide attempts. After gender-affirming treatment, adjustment varies, and while improvement in coexisting symptoms is often seen, some individuals continue to experience prominent anxiety and affective symptoms and remain at increased risk for suicide.

Case: 24-1714 Document: 78-2 Page: 52 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 181 Filed: 01/25/2024

Gender Dysphoria

519

A study of 572 children referred for gender identity concerns in Canada and several comparison groups (siblings, other referred children, and nonreferred children) largely from other high-income countries found that gender-referred children were 8.6 times more likely to self-harm or attempt suicide than comparison children, even after adjustment for overall behavior and peer relationship problems, and particularly in the second half of childhood. Among adolescents, the highest rate of suicide attempt is among transgender young men, followed by those defining themselves as neither male nor female.

Functional Consequences of Gender Dysphoria

Gender nonconformity may appear at all ages after the first 2–3 years of childhood and may interfere with daily activities. In older children, gender nonconformity may affect peer relationships and may lead to isolation from peer groups and to distress. Many children experience teasing and harassment or pressure to dress in attire associated with their birth-assigned sex, especially when growing up in a nonsupportive and nonaccepting environment. Also in adolescents and adults, the distress resulting from gender incongruence often interferes with daily activities. Relationship difficulties, including sexual relationship problems, are common, and functioning at school or at work may be impaired. Gender dysphoria is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of depression, suicidality, and other mental disorder co-occurrence, school dropout, and economic marginalization, including unemployment, with attendant social and mental health risks, especially in individuals who lack family or social support. In addition, these individuals' access to health services and mental health services may be impeded by structural barriers, such as institutional discomfort about, inexperience with, or hostility toward working with this patient population.

Differential Diagnosis

Nonconformity to gender roles. Gender dysphoria should be distinguished from simple nonconformity to stereotypical gender role behavior by the strong desire to be of another gender than the assigned one and by the extent and pervasiveness of gender-variant activities and interests. The diagnosis is not meant to merely describe nonconformity to stereotypical gender role behavior (e.g., "tomboyism" in girls, "girly-boy" behavior in boys, occasional cross-dressing in adult men). Given the increased openness of gender-diverse expressions by individuals across the entire range of the transgender spectrum, it is important that the clinical diagnosis be limited to those individuals whose distress and impairment meet the specified criteria.

Transvestic disorder. Transvestic disorder is diagnosed in heterosexual (or bisexual) adolescent and adult males (rarely in females) for whom women's clothing generates sexual excitement and causes distress and/or impairment without drawing their assigned gender into question. It is occasionally accompanied by gender dysphoria. An individual with transvestic disorder who also has clinically significant gender dysphoria can be given both diagnoses. In some cases of postpubertal-onset gender dysphoria in individuals assigned male at birth who are attracted to women, cross-dressing with sexual excitement is a precursor to the diagnosis of gender dysphoria.

Body dysmorphic disorder. An individual with body dysmorphic disorder focuses on the alteration or removal of a specific body part because it is perceived as abnormally formed, not because it represents a repudiated assigned gender. When an individual's presentation meets criteria for both gender dysphoria and body dysmorphic disorder, both diagnoses can be given. Individuals wishing to have a healthy limb amputated (termed by some body integrity identity disorder) because it makes them feel more "complete" usually do not wish to change gender, but rather desire to live as an amputee or a disabled person.

Autism spectrum disorder. In individuals with autism spectrum disorder, diagnosing gender dysphoria can be challenging. It can be difficult to differentiate potential co-occurring

Case: 24-1714 Document: 78-2 Page: 53 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 182 Filed: 01/25/2024

520 Gender Dysphoria

gender dysphoria from an autistic preoccupation because of the concrete and rigid thinking around gender roles and/or poor understanding of social relationships characteristic of autism spectrum disorder.

Schizophrenia and other psychotic disorders. In schizophrenia, there may rarely be delusions of belonging to some other gender. In the absence of psychotic symptoms, insistence by an individual with gender dysphoria that he or she is another gender is not considered a delusion. Schizophrenia (or other psychotic disorders) and gender dysphoria may co-occur. Gender-themed delusions may occur in up to 20% of individuals with schizophrenia. They can usually be differentiated from gender dysphoria by their bizarre content and by waxing and waning with remissions and exacerbations of psychotic episodes.

Other clinical presentations. Some individuals with an emasculinization desire who develop an alternative, nonmale/nonfemale gender identity do have a presentation that meets criteria for gender dysphoria. However, some males seek genital surgery for either aesthetic reasons or to remove psychological effects of androgens without changing male identity; in these cases, the criteria for gender dysphoria are not met.

Comorbidity

Clinically referred children with gender dysphoria show elevated levels of anxiety, disruptive, impulse-control, and depressive disorders. Autism spectrum disorder is more prevalent in clinically referred adolescents and adults with gender dysphoria than in the general population. Clinically referred adolescents and adults with gender dysphoria often have high rates of associated mental disorders, with anxiety and depressive disorders being the most common. Individuals who have experienced harassment and violence may also develop posttraumatic stress disorder.

Other Specified Gender Dysphoria

F64.8

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The other specified gender dysphoria category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording "other specified gender dysphoria" followed by the specific reason (e.g., "brief gender dysphoria," in which symptoms meet full criteria for gender dysphoria but the duration is less than the required 6 months).

Unspecified Gender Dysphoria

F64.9

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The unspecified gender dysphoria category is used in situations in which the clinician chooses not to specify the reason that the criteria are not met for gender dysphoria, and includes presentations in which there is insufficient information to make a more specific diagnosis.

Case: 24-1714 Document: 78-2 Page: 54 Filed: 10/31/2024 Case: 24-108 Document: 2-3

Page: 183 Filed: 01/25/2024

DECLARATION OF NATALIE ROSE KASTNER

I, Natalie Rose Kastner, declare as follows:

I make this declaration based on personal knowledge, and, if called as a witness, I 1. could and would testify competently to the matters stated herein.

2. I am a veteran of the United States Army. I served as Combat Engineer (21B) from 2006 to 2008. I completed basic training at Fort Leonard Wood, Missouri, after which I was stationed at Fort Drum, New York. During my time in service, I was promoted from Private (E-1) to Private First Class (E-3). I was honorably discharged for medical reasons.

3. I am a transgender woman. I am a member of the Transgender American Veterans Association ("TAVA"). I joined the organization in 2022.

I live in Texarkana, Texas. I have three children who reside with their mother, 4. also in Texas.

5. In March 2022, I was diagnosed with gender dysphoria by Dr. Mark J. Starr, a Veteran Health Administration ("VHA") provider at the Southern Arizona Veterans Affairs ("VA") Health Care System. Since July 2022, I have been undergoing hormone replacement therapy ("HRT") under the care of Dr. Shristi Lamichhane at the Overton Brooks VA Medical Center.

6. I have no medical training, besides the U.S. Army Combat Lifesaver Course that I completed during my time in service. Nevertheless, knowing that gender-confirmation surgery was not available from VA and was prohibitively expensive otherwise, I removed my right testicle at home on March 5, 2022, out of desperation. I did so without anesthesia. While

¹ My legal name is Joshua Nathanial Kastner, but until I succeed in changing my name legally, I use the preferred name Natalie Rose Kastner.

Appx429

Case: 24-1714 Document: 78-2 Page: 55 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 184 Filed: 01/25/2024

removing my testicle, I severed an artery, which could have killed me. I did not intend suicide; I intended to correct my body.

- 7. I drove myself to the nearest hospital emergency room. There, I received life-saving medical care.
- 8. I cannot imagine how many transgender women, without access to adequate medical care, have taken matters into their own hands and died. I am grateful that I am alive to share my story.
- 9. I informed the VA Texarkana Outpatient Clinic of my life-threatening incident in March 2022.
- 10. In Summer 2023, I asked my primary care physician at the VA Texarkana Outpatient Clinic, Dr. Mary O. Mbonu, about receiving gender-confirmation surgery. Dr. Mbonu referred me to VHA Directive 1341(3), which states "VA does not provide gender confirming/affirming surgeries in VA facilities or through non-VA care." Because I am facially ineligible and so it would be futile to request the treatment, I have not formally requested gender-confirmation surgery at VA.
- 11. If I had access through VA, I would pursue gender-confirmation surgery, including orchiectomy, vaginoplasty, and electrolysis.
- 12. I am currently not enrolled in civilian health insurance, so VA is my sole health care provider.
- 13. I have repeatedly attempted to access gender-confirmation surgery through civilian health insurance—including Blue Cross Blue Shield, Cigna, and the Health Insurance Marketplace—to no avail. I was formerly enrolled in the Blue Cross Blue Shield Medicare Advantage plan. Despite my best efforts, Blue Cross Blue Shield representatives informed me

Case: 24-1714 Document: 78-2 Page: 56 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 185 Filed: 01/25/2024

that the insurance would not cover gender-confirmation surgery in the state of Texas. I understand that under Texas policies, gender-confirmation surgery is considered an elective surgery, and Blue Cross Blue Shield Medicare Advantage will cover only gender-confirmation surgery that is deemed "medically necessary."

- 14. I cannot afford to pay for gender-confirmation surgery out of pocket. Having consulted with various providers, I estimate that gender-confirmation surgery would cost, at a minimum, \$60,000. I am disabled and unable to work; I have a 70% VA disability rating. I rely on my VA disability compensation and Social Security benefits to live. I simply do not have the funds to access gender-confirmation surgery without insurance coverage.
- 15. As a result, I have been forced to consider relocating to a state, such as Illinois, where my gender-confirmation surgery might be covered by the Blue Cross Blue Shield Medicare Advantage plan. Such a move would be deeply painful and disruptive. I love my town and I have found a supportive community here. I love living in the same state as my children. But VA's delay in providing gender-confirmation surgery forces me to choose between necessary medical care and my children, friends, and family. It is an impossible choice.
- 16. VA's refusal to provide gender-confirmation surgery not only exacerbates my gender dysphoria, but also risks worsening my Type 2 diabetes. Without an orchiectomy, I continue to have a testis, which produces testosterone. To block that testosterone and manage my gender dysphoria, I must take spironolactone. Unfortunately, spironolactone can increase hemoglobin A1C and decrease kidney function. My lab results show that my kidney function went from normal (Stage G1) in March 2023 to Mild Decrease (Stage G2) in January 2024.
- 17. On March 10, 2023, I conveyed my concern about the impact of spironolactone on my diabetes in an appointment with Dr. Mbonu. Dr. Mbonu referred again to VA Directive

Case: 24-1714 Document: 78-2 Page: 57 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 186 Filed: 01/25/2024

1341(3) and stated that the VA could not provide me with an orchiectomy. She also stated that,

because my kidneys did not show dangerously reduced function, there was no reason for her to

refer me for an orchiectomy.

18. It is difficult to put into words how profoundly and negatively I am affected by

the VHA's policy of denying gender-confirmation surgery to people like me. Every day that the

VA delays its response to TAVA's petition, I grapple with feelings of despair. I am trapped in a

state of limbo that daily damages every aspect of my life, from my physical and mental health to

my ability to sustain family relationships. I often regret not removing my second testicle that

night in March 2022, even though I know it may have killed me. I feel that I am left with no

viable options to live a full and dignified life.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true

and correct to the best of my information and belief.

Dated: 18/Jan /2024

Natalie Rose Kastner (Joshua

Nathanial Kastner)

Case: 24-1714 Document: 78-2 Page: 58 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 187 Filed: 01/25/2024

DECLARATION OF RAY GIBSON

I, Ray Gibson, declare as follows:

1. I make this declaration based on personal knowledge, and, if called as a witness, I

could and would testify competently to the matters stated herein.

2. I am a veteran of the United States Air Force. I served as Data Processing Specialist

from 1978 to 1981. I was stationed at the Sunnyvale (Onizuka) Air Force Station. During my time

in service, I was promoted from Airman Basic (E-1) to Airman First Class (E-3). I also received

an Airman of the Quarter award. I was honorably discharged.

3. I am a Black transgender man, and I am a member of the Transgender American

Veterans Association ("TAVA").

4. I am 66 years old, and I live in the Atlanta, Georgia metro area.

5. I knew that I was transgender when I was six years old. I told my cousins that I

joined the service to become a better man.

6. While in the Air Force, I did not identify as transgender. I did not know the words

to describe myself at that time, and I did not know that there were people like me that existed. I

felt that I had to hide my identity to remain in military service.

7. I spoke with my primary care provider, Dr. Subha Parchuri, about being transgender

in 2014. I was diagnosed with gender dysphoria that same year at the Lawrenceville U.S.

Department of Veterans Affairs ("VA") Clinic. Since October 2015, I have been undergoing

hormone replacement therapy under the care of Dr. Vin Tangpricha at the Atlanta VA Medical

Center ("VAMC").

1 AR1153 Appx433 Case: 24-1714 Document: 78-2 Page: 59 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 188 Filed: 01/25/2024

8. After service, I worked my way up to being a software consultant without a college

degree. In 2006, I received a Bachelor of Arts in Information Technology from American

Intercontinental University Online.

9. I retired in 2001 for health reasons. I am disabled and unable to work. I have

depression, high blood pressure, chronic obstructive pulmonary disease, and kidney disease. Since

2003, I have also required a cane and sometimes a walker to walk due to neuropathy in my toes.

10. I receive disability compensation benefits from the VA, which has assigned me a

90% disability rating. I also have a 100% Social Security benefit rating.

11. In 2017, I asked my endocrinologist at the Atlanta VAMC about accessing

mastectomy surgery. He informed me that I may be eligible for a mastectomy because there is a

history of breast cancer in my family. But the VA would not cover the cost of tests that a living

relative with breast cancer would need to undertake. I did not feel comfortable asking my only

living relative with breast cancer to undertake these tests out of pocket, so that I might be eligible

for a mastectomy.

12. I have always been and will always be my own advocate, but I am tired. I am

exhausted by the challenges of being my own advocate. I am tired of fighting for the care that I so

desperately need and deserve.

13. In 2021, I was forced to access mastectomy surgery outside of VA. VA is my sole

health care provider. Without civilian health insurance, I had to cover the cost of my surgery and

associated costs entirely out-of-pocket. My surgery cost over \$8,000. I also covered the cost of my

travel from Georgia to Dallas, Texas, in addition to my one week stay at a hotel to recover from

surgery.

Case: 24-1714 Document: 78-2 Page: 60 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 189 Filed: 01/25/2024

14. I am not satisfied with the results of my mastectomy. Even though the VA covers

post-operative care per Veterans Health Administration ("VHA") Directive 1341(3), I have yet to

be able to access this care through Atlanta VAMC Community Care. VA staff, in my experience,

are unsure what qualifies as eligible care under VHA Directive 1341(3). Being denied post-

operative care at the Atlanta VAMC has been humiliating. Every day that I am denied post-

operative care, I feel dehumanized by VA staff.

15. In addition to being denied post-operative care, I have been unable to access other

VA-covered gender-affirming care at the Covington VA Clinic. The Covington VA Clinic is about

five minutes away from my house, but I have been told by staff there that they do not treat

transgender patients. I am forced to access some gender-affirming care at a civilian health clinic

nearby, and drive over an hour away to the Lawrenceville VA Clinic to access all remaining care.

16. If I had access through VA, I would pursue additional gender-confirmation surgery,

including phalloplasty. I also desire post-operative care for my mastectomy.

17. Because I am facially ineligible and so it would be futile to request the treatment, I

have not formally requested phalloplasty at VA. As I live on a fixed income, it is currently

impossible for me to save enough money to ever be able to afford phalloplasty out of pocket. I

have been homeless several times in my life. To survive these periods of homelessness, I used up

my entire life savings. Every year, I apply for public scholarships to help cover the cost of

phalloplasty surgery. I believe that this surgery would cost me around \$250,000.

18. Not being able to access bottom surgery has negatively affected my entire life, from

my standard of living to my dating life. If the VA does not provide access to gender-confirmation

surgery, then people like me will be destined to a life of dysphoria. My gender dysphoria is

suffocating.

AR1

Case: 24-1714 Document: 78-2 Page: 61 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 190 Filed: 01/25/2024

19. I am old. I am racing against the ticking clock of my own health and age. Recovering from surgeries only gets harder and harder as I get older. The primary surgery I am interested in accessing, phalloplasty, requires multiple surgeries and long recovery periods. I fear that I will soon be too old to safely undergo this life-saving surgery.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

Dated: 01/20/2024

Ray Sibson

Case: 24-1714 Document: 78-2 Page: 62 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 191 Filed: 01/25/2024

DECLARATION OF REBEKKA ESHLER

I, Rebekka Eshler, declare as follows:

1. I am the National President and a current board member of the Transgender

American Veterans Association ("TAVA"). I have personal knowledge of the matters stated in

this declaration and could and would so testify if called as a witness.

2. I am a veteran of the United States Army. I was stationed at Joint Base Elmendorf-

Richardson in Anchorage, Alaska. I served as a Forward Observer from 2012 to December 2015.

I was honorably discharged.

3. After my discharge, I received a Bachelor of Arts from University of Alaska

Anchorage ("UAA"). At UAA, I served as the Student Veterans of America Chapter President and

volunteered for an organization that provides medical response to natural disasters and

humanitarian crises around the world.

4. Since 2019, I have worked as an Emergency Medical Technician ("EMT") at a

homeless shelter in Alaska. In 2022, I was crowned Miss Trans Alaska. I went on to represent the

State of Alaska at the Miss Trans USA 2022 pageant where I won Miss Congeniality.

5. During my service, I did not identify as transgender. I now believe that part of the

reason I went into the military was to prove myself to friends and family who doubted my identity.

In the Summer of 2018, I was diagnosed with gender dysphoria by Dr. Camilla Madden at the

Anchorage U.S. Department of Veterans Affairs ("VA") Medical Center. Since September 2018,

I have been undergoing hormone replacement therapy under the care of several different providers

at the Anchorage VA Medical Center.

6. In 2019, knowing that VA did not cover gender-confirmation surgery, I asked for a

referral letter for facial feminization surgery from the nurse at the Anchorage VA Medical Center

AR1157 Appx437 Case: 24-1714 Document: 78-2 Page: 63 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 192 Filed: 01/25/2024

who oversaw my hormone therapy. She supported my decision to access facial feminization

surgery outside of the VA, but she did not believe that she was authorized under Veterans Health

Administration ("VHA") Directive 1341(3) to refer me for gender-confirmation surgery. I was

forced to pay for a non-VA provider, whom I did not regularly see, to write a referral letter for

facial feminization surgery.

7. I have been involved in TAVA since 2021, when I joined TAVA's board as the

Director of Strategic Partnerships and Collaborations. In August 2022, I was elected President. My

duties include building coalitions with other advocacy groups, developing relationships with

organizations and individuals that align with our mission, influencing policy at VA, and setting

public policy goals to assist transgender veterans. My duties also include recruiting, growing, and

mentoring our membership, and providing support and outreach to transgender veterans on a range

of issues, including accessing health care and changing identity documents.

8. TAVA is a 501(c)(3) organization that was founded in 2003 to advocate on behalf

of transgender veterans within the VHA system. As one of the only national organizations focused

exclusively on advocating on behalf of transgender veterans, TAVA is a leading voice and source

of information for the transgender veteran community. Its mission is to work with VA, Congress,

veterans, active-duty military personnel, and other veteran and LGBTQ advocacy groups to

influence VA policy, regulations, and procedures regarding the provision of health care to veterans

with gender dysphoria and to ensure that transgender veterans receive necessary and appropriate

care. While TAVA primarily focuses on ensuring the fair and equal treatment of transgender

individuals, it is committed to improving the health care of all American veterans.

9. TAVA's advocacy goals include: assisting veterans in navigating the VHA system,

improving the quality and breadth of health care and other services provided to transgender service

4**R**1

Appx438

Case: 24-1714 Document: 78-2 Page: 64 Filed: 10/31/2024

Case: 24-108 Document: 2-3 Page: 193 Filed: 01/25/2024

members through VA, helping veterans correct name and gender information on military records,

engaging in veteran suicide prevention efforts, and addressing transgender veteran homelessness,

among other goals. TAVA also works with transgender individuals to assist them in securing VA

benefits for themselves and their spouses and family. TAVA works towards these goals by

educating VA as well as serving as a liaison between transgender veterans and VA to raise

members' issues with staff and to connect members to appropriate resources.

10. TAVA has spent considerable time and resources on educating veterans,

policymakers, and others about the exclusion of medically necessary gender-confirmation surgery

from VA's medical benefits package, and on addressing the needs of transgender veterans affected

by this exclusion. For example, we have produced educational materials for transgender veterans

about the gender-affirming care that VA provides and its exclusion of coverage for gender-

confirmation surgery. We have also prepared educational reports that include discussion of the

harms caused by the surgery exclusion and sponsored community gatherings to discuss strategies

to end this exclusion.

11. We have also spent considerable time and resources due to VA's delay in

addressing TAVA's 2016 rulemaking petition regarding gender-confirmation surgery. For

instance, TAVA prepared a comment to submit during the notice-and-comment period it

anticipated would timely follow Secretary McDonough's 2021 promises that VA would provide

gender-confirmation surgery. TAVA leadership also traveled to and engaged in meetings about

how to implement this change to the medical benefits package. But these efforts have been futile

thus far, as VA has failed to follow through on Secretary McDonough's assurances.

12. In my roles as TAVA's Director of Strategic Partnerships & Collaborations and

now President, I have communicated with veterans across the country about the VA's exclusion

R

Appx439

Case: 24-1714 Document: 78-2 Page: 65 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 194 Filed: 01/25/2024

of gender-confirmation surgery and how it affects them. Our Board members have also spoken with national news outlets in an effort to educate the public about the VA's exclusion of gender-

confirmation surgery and to call for reform.

13. TAVA has approximately 5,400 members throughout the country who have joined

our mission through social media and, even though a significant percentage of those members are

low-income, have volunteered time and resources to help the organization achieve its goals.

14. According to recent estimates, TAVA represents the interests of an estimated

163,000 transgender veterans of the U.S. Military.

15. Many of TAVA's members are transgender veterans currently enrolled at the VA.

Some of those individuals have been diagnosed with gender dysphoria by VA and have been

provided medical care related to their diagnosis. However, some members who have sought

gender-confirmation surgery through VA, or coverage of such surgery by VA, have been denied

such surgery or coverage because of the existing regulatory exclusion of "gender alterations" from

covered benefits. Indeed, in every year from 2016 to 2023, multiple TAVA members have been

denied gender-confirmation surgery by VA. Many of those veterans rely on the VA for the

provision of their physical and mental health care, and many satisfy all the medical prerequisites

for gender-confirmation surgery: they have been diagnosed with gender dysphoria (often by VA

clinicians), they have spent multiple years living in a gender role consistent with their gender

identity and are currently undergoing hormone therapy to assist in their transition, and they have

been prescribed gender-confirmation surgery by qualified medical providers as medically

necessary treatment for their condition. Nevertheless, these veterans have been unable to obtain

medically necessary gender-confirmation surgery due to the VA's categorical exclusion of this

surgery from its medical benefits package.

Case: 24-1714 Document: 78-2 Page: 66 Filed: 10/31/2024 Case: 24-108 Document: 2-3 Page: 195 Filed: 01/25/2024

Ç

16. In submitting this petition, TAVA advocates on behalf of its members whose

mental and physical health daily deteriorates while waiting for medically necessary treatment as a

result of the VA's delay. Without a response, TAVA members are left in a state of limbo, unable

to make important life plans. Relying on the VA's repeated assurances that it plans to provide

gender-confirmation surgery, veterans are hesitant to upend their lives, families, and finances in

an attempt to access such surgery through alternative means. Some TAVA members are

considering leaving their families and moving to a different state, where their civilian health

insurance might cover gender-confirmation surgery. Other TAVA members are facing the

impossible prospect of draining their life savings or going into debt to pay for gender-confirmation

surgery out of pocket. If the VA were to formally respond, one way or another, TAVA members

would be able to plan to access this medically necessary care.

17. Many TAVA members have been prescribed, and desire to receive, medically

necessary transition-related surgeries, but the VA's delay in providing a formal response to the

rulemaking petition has prevented them from making plans to receive this care. Many TAVA

members have experienced and continue to experience extreme and sometimes life-threatening

hardships because they still have not obtained coverage for these health care services that their

doctors deem to be medically necessary.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true

and correct to the best of my information and belief.

Dated:

Rebekka Eshler

Department of Veterans Affairs

Memorandum

Date February 22, 2024

From: Secretary (00)

Analysis of Amendment to 38 C.F.R. § 17.38(c)(4) and PACT Act Eligibility (VIEWS 11428675)

To Under Secretary for Health (10)

- 1. VA has moved methodically in its consideration of an important change to its medical benefits package to provide gender affirming surgery, in addition to the Gender Affirming Care VA presently provides. Any potential change in coverage must be implemented in a manner that has been thoroughly considered and ensures that the services made available to Veterans meet VA's rigorous standards for consistent and quality health care nationwide.
- 2. In 2022, Congress passed the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022 (the PACT Act), one of the most significant laws ever to help millions of veterans who were exposed to toxins and burn pits during their military service. Under the accelerated schedule for PACT Act Section 103 implementation, next month any toxin-exposed Veteran who served during any conflict outlined in the PACT Act will be able to enroll and become newly eligible for hospital care (including mental health services and counseling), medical services, and nursing home care for any illness. This influx of new patients has the potential to change how, where, and at what cost VA provides health care.
- 3. VA's prior analyses of the impact of an amendment to 38 C.F.R. § 17.38(c)(4) to remove the gender alteration exclusion have not considered or addressed the PACT Act's expansion of eligibility for Veterans Health Administration (VHA) hospital care and medical services.
- 4. To ensure that the potential impact of this expansion of coverage has been thoroughly considered, I request that VHA provide the following data and estimates to the Office of the Secretary of Veterans Affairs:
 - a. Pre-Implementation Data and Estimates
 - Annual data on number of trans-Veterans who sought care or services through VHA since 2016.
 - VHA estimates within the population of Veterans who will be newly eligible for care and services under PACT Act Section 103:
 - Transgender Veterans.
 - Transgender Veterans who will seek any care or service through VHA.
 - Transgender Veterans who would require gender affirming surgery if offered by VHA.

Page 2.

Subj: Analysis of Amendment to 38 C.F.R. § 17.38(c)(4) and PACT Act Eligibility (VIEWS 11428675)

- b. Post-Implementation Data. Data reported per month over four months (March (partial), April, May, June 2024), disaggregated by individual Veterans Integrated Services Networks, concerning the number of Veterans who became newly eligible for care and services under PACT Act Section 103:
 - Number of transgender Veterans who sought any care or service through VHA.
 - ii. Number of transgender Veterans who would require *gender affirming* surgery if offered by VHA.
- Utilizing those data and estimates, VHA should:
 - a. Determine how existing eligibility standards for Beneficiary Travel (BT) will impact utilization of gender affirming surgery if those surgeries are only offered at specific surgery centers within the VHA network. The Regulatory Impact Analysis (RIA) VA previously submitted to the Office of Management and Budget assumed that the transgender Veterans who require surgery would be eligible for BT. VA has not yet examined or analyzed how many transgender Veterans would in fact be eligible for BT. The requested estimates and data, disaggregated by individual VISN, will provide information concerning the population and distribution of the transgender Veteran community to inform an analysis of utilization;
 - b. Consider and analyze whether a unique clinical appeals process for gender affirming surgery is necessary or warranted and if so, design that process. Typically, clinical appeals are decided at the VISN-level. For some benefits or services, typically those with specific and complex clinical indicators, VHA has established a unique clinical appeals process. The complex and specialized determination of a patient's clinical requirement for gender affirming surgery merits consideration and analysis of a unique clinical appeals process. The requested estimates and data, disaggregated by individual VISN, will provide information concerning the population and distribution of the transgender Veteran community to inform that consideration and analysis; and
 - c. Determine if the Notice of Proposed Rulemaking or RIA VA previously submitted to the Office of Management and Budget must be updated in light of these estimates, data, and analyses.
- 6. I request that VHA respond to this memorandum with the described estimates, data, and analyses no later than July 31, 2024. VHA should produce its estimates, collect the data, and analyze these matters in a manner that maintains the anonymity and protects the privacy of all Veterans.

Denis McDonologh

Case: 24-1714 Document: 78-2 Page: 69 Filed: 10/31/2024



ERVICE TRANSITION FOR TRANSGENDER SERVIC

WEMBERS IN-SERVICE TRANSITION FOR TRANSGENDER SERVICE

DOD INSTRUCTION 1300.28

Originating Component: Office of the Under Secretary of Defense for Personnel and Readiness

Effective: April 30, 2021 (This issuance supersedes any previously published

contradictory guidance).

Change 1 Effective: December 20, 2022

Releasability: Cleared for public release. Available on the Directives Division Website

at https://www.esd.whs.mil/DD/.

Reissues and Cancels: DoD Instruction 1300.28, "Military Service by Transgender Persons and Persons and Prepared 20020.

Persons with Gender Dysphoria," September 4, 2020

Approved by: Virginia S. Penrod, Acting Under Secretary of Defense for Personnel and

Keadiness

Change 1 Approved by: Gilbert R. Cisneros, Jr., Under Secretary of Defense for Personnel and Readiness

Purpose: In accordance with the authority in DoD Directive 5124.02, this issuance establishes policy, assigns responsibilities, and prescribes procedures:

- Regarding the process by which Service members may transition gender while serving.
- For changing a Service member's gender marker in the Defense Enrollment Eligibility Reporting System (DEERS).
- For medical care for Active Component (AC) and Reserve Component (RC) transgender Service members.

DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

TABLE OF CONTENTS

SECTION 1: GENERAL ISSUANCE INFORMATION	3
1.1. Applicability	3
1.2. Policy	3
1.3. Summary of Change 1.	3
Section 2: Responsibilities	4
2.1. Under Secretary of Defense for Personnel and Readiness (USD(P&R))	
2.2. Assistant Secretary of Defense for Manpower and Reserve Affairs	4
2.3. Assistant Secretary of Defense for Health Affairs	4
2.4. Director, Defense Health Agency (DHA)	
2.5. Secretaries of the Military Departments and Commandant, USCG	
Section 3: Gender Transition	6
3.1. General.	
3.2. Special Military Considerations.	7
a. Medical	
b. In-Service Transition.	8
c. Continuity of Medical Care	8
d. Living in Self-Identified Gender	
e. DEERS.	
f. Military Readiness.	
3.3. Roles and Responsibilities.	
a. Service Member's Role.	
b. Military Medical Provider's Role.	
c. Commander's Role	
d. Role of the Military Department and the USCG.	
3.4. Gender Transition Approval Process.	12
3.5. Considerations Associated with RC personnel.	13
a. Gender Transition Approach.	13
b. Diagnosis and Medical Treatment Plans	13
c. Selected Reserve Drilling Member Participation	
d. Delayed Training Program (DTP).	
e. Split Option Training.	
3.6. Considerations Associated with the First Term of Service	14
SECTION 4: ADDITIONAL POLICY GUIDANCE	16
4.1. Equal Opportunity	
4.2. Protection of PII and PHI.	
4.3. Personal Privacy Considerations	
4.4. Assessment and Oversight of Compliance.	
GLOSSARY	18
G.1. Acronyms.	
G.2. Definitions	
References	22

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

- a. This issuance applies to OSD, the Military Departments (including the United States Coast Guard (USCG) at all times, including when it is a Service in the Department of Homeland Security, by agreement with that Department), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD.
 - b. The requirement in Paragraph 2.5.e. of this issuance does not apply to the USCG.
- c. For the purpose of this issuance, the term "Service member" includes cadets and midshipmen in a contracted Reserve Officer Training Corps (ROTC) status and those at the Military Service Academies. This issuance does not apply to individuals participating in ROTC programs in a non-contracted volunteer status. Contracted ROTC midshipmen and cadets have limited eligibility for medical benefits and care through a military medical treatment facility (MTF), delineated in DoD Instruction (DoDI) 1215.08.

1.2. POLICY.

- a. DoD and the Military Departments will institute policies to provide Service members a process by which they may transition gender while serving. These policies are based on the conclusion that open service by transgender persons who are subject to the same high standards and procedures as other Service members with regard to medical fitness for duty, physical fitness, uniform and grooming standards, deployability, and retention is consistent with military service and readiness.
- b. All Service members must be treated with dignity and respect. No person, solely on the basis of his or her gender identity, will be:
 - (1) Involuntarily separated or discharged from the Military Services;
 - (2) Denied reenlistment or continuation of service in the Military Services; or
 - (3) Subjected to adverse action or mistreatment.

1.3. SUMMARY OF CHANGE 1.

The change to this issuance:

- a. Adds transgender data related guidance pursuant to DoDI 6400.11.
- b. Updates references for accuracy.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

SECTION 2: RESPONSIBILITIES

2.1. UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS (USD(P&R)).

The USD(P&R):

- a. Evaluates any proposed new Military Department and Military Service regulations, policies, and guidance related to military service by transgender persons and persons with gender dysphoria, and revisions to such existing regulations, policies, and guidance, to ensure consistency with this issuance.
- b. Issues guidance to the Military Departments, establishing the prerequisites and procedures for changing a Service member's gender marker in DEERS.

2.2. ASSISTANT SECRETARY OF DEFENSE FOR MANPOWER AND RESERVE AFFAIRS.

Under the authority, direction, and control of the USD(P&R), the Assistant Secretary of Defense for Manpower and Reserve Affairs coordinates with the Assistant Secretary of Defense for Health Affairs in the management and implementation of this policy, and issues clarifying guidance, as appropriate.

2.3. ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS.

Under the authority, direction, and control of the USD(P&R), the Assistant Secretary of Defense for Health Affairs coordinates with the Assistant Secretary of Defense for Manpower and Reserve Affairs in the management and implementation of health care matters associated with this policy, and issues clarifying guidance, as appropriate.

2.4. DIRECTOR, DEFENSE HEALTH AGENCY (DHA).

Under the authority, direction, and control of the USD(P&R), through the Assistant Secretary of Defense for Health Affairs, the Director, DHA:

- a. Provides or coordinates guidance and oversight, as appropriate, to standardize the provision of medically necessary health care for transgender Service members diagnosed with gender dysphoria, including members for whom gender transition is determined to be medically necessary by a medical provider.
- b. Oversees the development and use of clinical practice guidelines to support the medical treatment plan and projected schedule for treatment of Service members diagnosed with gender dysphoria.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

c. Oversees the development and use of clinical practice guidelines to support the continuity of care for Service members diagnosed with gender dysphoria.

- d. Establishes procedures to require that education and training on transgender health care are conducted in MTFs.
- e. Ensures appropriate standards and procedures under the Supplemental Health Care Program for transgender health care services.

2.5. SECRETARIES OF THE MILITARY DEPARTMENTS AND COMMANDANT, USCG.

The Secretaries of the Military Departments and the Commandant, USCG:

- a. Adhere to all provisions of this issuance.
- b. Administer their respective programs, and update existing Military Department regulations, policies, and guidance, or issue new issuances, as appropriate, in accordance with the provisions of this issuance.
- c. Maintain a Service central coordination cell (SCCC) to provide multi-disciplinary (e.g., medical, mental health, legal, military personnel management) expert advice and assistance to commanders with regard to service by transgender Service members and gender transition in the military, and to assist commanders in the execution of DoD, Military Department, and Service policies and procedures.
- d. Educate their respective AC and RC forces to ensure an adequate understanding within those forces of policies and procedures pertaining to gender transition in the military.
- e. Submit to the USD(P&R) the text of any proposed revision to existing Military Department and Service regulations, policies, and guidance, and of any proposed new issuance, at least 15 business days in advance of the proposed publication date. In accordance with Paragraph 1.1.b. of this issuance, this requirement does not apply to the USCG.
- f. Provide oversight regarding the implementation of this issuance and any Military Department and Military Service regulations, policies, and guidance related to military service by transgender persons and persons with gender dysphoria, the protection of personally identifiable information (PII), protected health information (PHI), and personal privacy considerations, consistent with current DoD guidance and in accordance with Paragraphs 4.2. and 4.3. of this issuance.
- g. Implement processes for the assessment and oversight of compliance with DoD, Military Department, and Service policies and procedures applicable to service by transgender persons, and persons with gender dysphoria, in accordance with Paragraph 4.4. of this issuance.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

SECTION 3: GENDER TRANSITION

3.1. GENERAL.

- a. Except where an exception to policy (ETP) has been granted transgender Service members will be subject to the same standards as all other Service members. When a standard, requirement, or policy depends on whether the individual is male or female (e.g., medical fitness for duty; physical fitness and body fat standards; berthing, bathroom, and shower facilities; and uniform and grooming standards), all Service members will be subject to the standard, requirement, or policy associated with their gender marker in DEERS.
- b. The Military Departments and Services recognize a Service member's gender by the Service member's gender marker in DEERS. Consistent with that gender marker, the Services apply, and the Service member must meet, all standards for uniforms and grooming; body composition assessment (BCA); physical readiness testing (PRT); Military Personnel Drug Abuse Testing Program (MPDATP) participation; and other military standards applied with consideration of the Service member's gender. For facilities subject to regulation by the military, Service members will use those berthing, bathroom, and shower facilities associated with their gender marker in DEERS.
- c. Service members with a diagnosis that gender transition is medically necessary will receive associated medical care and treatment from a medical provider. The recommendations from a military medical provider will address the severity of the Service member's medical condition and the urgency of any proposed medical treatment. Medical providers will provide advice to commanders in a manner consistent with processes used for other medical conditions that may limit the Service member's performance of official duties.
- d. Any medical care and treatment provided to an individual Service member in the process of gender transition will be provided in the same manner as other medical care and treatment. Nothing in this issuance will be construed to authorize a commander to deny medically necessary treatment to a Service member.
- e. Any determination that a transgender Service member is non-deployable at any time will be consistent with established Military Department and Service standards, as applied to other Service members whose deployability is similarly affected in comparable circumstances unrelated to gender transition.
- f. Commanders will assess expected impacts on mission and readiness after consideration of the advice of military medical providers and will address such impacts in accordance with this issuance. In applying the tools described in this issuance, a commander will not accommodate biases against transgender individuals. If a Service member is unable to meet standards or requires an ETP during a period of gender transition, all applicable tools, including the tools described in this issuance, will be available to commanders to minimize impacts to the mission and unit readiness.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

g. When a cognizant military medical provider determines that a Service member's gender transition is complete, and at a time approved by the commander in consultation with the Service member concerned, the Service member's gender marker will be changed in DEERS and the Service member will be recognized in the self-identified gender.

3.2. SPECIAL MILITARY CONSIDERATIONS.

Gender transition while serving in the military presents unique challenges associated with addressing the needs of the Service member in a manner consistent with military mission and readiness. Where possible, gender transition should be conducted such that a Service member would meet all applicable standards and be available for duty in the birth gender before a change in the Service member's gender marker in DEERS and would meet all applicable standards and be available for duty in the self-identified gender after the change in gender marker. However, since every transition is unique, the policies and procedures set forth herein provide flexibility to the Military Departments, Services, and commanders, in addressing transitions that may or may not follow this construct. These policies and procedures are applicable, in whole or in relevant part, to Service members who intend to begin transition, are beginning transition, who already may have started transition, and who have completed gender transition and are stable in their self-identified gender.

a. Medical.

- (1) In accordance with DoDIs 6025.19 and 1215.13, all Service members must maintain their health and fitness, meet individual medical readiness requirements, and report to their chains of command any medical (including mental health) and health issue that may affect their readiness to deploy or fitness to continue serving.
- (2) Each Service member in the AC or in the Selected Reserve will, as a condition of continued participation in military service, report significant health information to their chain of command. Service members who have or have had a medical condition that may limit their performance of official duties must consult with a military medical provider concerning their diagnosis and proposed treatment, and must notify their commanders.
- (3) When a Service member receives a diagnosis of gender dysphoria from a military medical provider and obtains a medical treatment plan for gender transition, the Service member's notification to the commander must identify all medically necessary care and treatment that is part of the Service member's medical treatment plan.
- (a) If applicable, the Service member's notification to the commander must identify a projected schedule for such treatment and an estimated date for a change in the Service member's gender marker in DEERS.
- (b) If additional care and treatment are required after a gender marker change that was not part of an original treatment plan, the Service member must provide notification to the commander identifying the additional care, treatment, and projected schedule for such treatment.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

(c) Recommendations of a military health care provider will address the severity of the Service member's medical condition and the urgency of any proposed medical treatment.

b. In-Service Transition.

Gender transition begins when a Service member receives a diagnosis from a military medical provider indicating that gender transition is medically necessary, and then completes the medical care identified or approved by a military mental health or medical provider in a documented treatment plan as necessary to achieve stability in the self-identified gender. It concludes when the Service member's gender marker in DEERS is changed and the Service member is recognized in his or her self-identified gender. Care and treatment may still be received after the gender marker is changed in DEERS as described in Paragraph 3.2.c. of this issuance, but at that point, the Service member must meet all applicable military standards in the self-identified gender. With regard to facilities subject to regulation by the military, a Service member whose gender marker has been changed in DEERS will use those berthing, bathroom, and shower facilities associated with his or her gender marker in DEERS.

c. Continuity of Medical Care.

A military medical provider may determine certain medical care and treatment (e.g., cross-sex hormone therapy) to be medically necessary even after a Service member's gender marker is changed in DEERS. A gender marker change does not preclude such care and treatment. If additional care and treatment are required after a gender marker change that was not part of an original treatment plan, and that change may impact the Service member's fitness for duty the Service member must provide, medical documentation to the commander identifying the additional care, treatment, and projected schedule for such treatment.

d. Living in Self-Identified Gender.

Each Military Department and Service may issue policy regarding the application of real life experience (RLE), including RLE in an on-duty status before gender marker change in DEERS.

e. DEERS.

Except when an exception has been granted in accordance with Paragraph 3.2.d. or 3.2.f. of this issuance, a Service member's gender is recognized by the Service member's gender marker in DEERS. Coincident with that gender marker, the Services apply, and the Service member must meet, all standards for uniforms and grooming; BCA; PRT; MPDATP participation; and other military standards applied with consideration of the Service member's gender.

f. Military Readiness.

Unique to military service, the commander is responsible and accountable for the overall readiness of his or her command. The commander is also responsible for the collective morale, welfare, good order, and discipline of the unit, and establishing a command climate that creates an environment where all members of the command are treated with dignity and respect. When a commander receives any request from a Service member that entails a period of non-availability for duty (e.g., necessary medical treatment, ordinary leave, emergency leave,

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

temporary duty, other approved absence), the commander must consider the individual need associated with the request and the needs of the command in making a decision on that request.

3.3. ROLES AND RESPONSIBILITIES.

a. Service Member's Role.

The Service member will:

- (1) Secure a medical diagnosis from a military medical provider.
- (2) Notify the commander of a diagnosis indicating gender transition is medically necessary. This notification will identify all medically necessary treatment in their medical treatment plan and a projected schedule for such treatment, including an estimated date for a change in the Service member's gender marker in DEERS, pursuant to Paragraph 3.2.a. of this issuance.
- (3) Notify the commander of any change to the medical treatment plan, the projected schedule for such treatment, or the estimated date on which the Service member's gender marker will be changed in DEERS.
- (4) Notify the commander of any new care determined to be medically necessary after a gender marker change in DEERS that was not previously approved in the medical treatment plan, in accordance with Paragraph 3.2.a.(3) of this issuance, as such care or treatment may affect readiness to deploy or fitness to continue serving.

b. Military Medical Provider's Role.

The military medical provider will:

- (1) Establish the Service member's medical diagnosis, recommend medically necessary care and treatment, and, in consultation with the Service member, develop a medical treatment plan associated with the Service member's gender transition, pursuant to Paragraph 3.1.a. of this issuance, for submission to the commander.
- (2) In accordance with established military medical practices, advise the commander on the medical diagnosis applicable to the Service member, including the provider's assessment of the medically necessary care and treatment, the urgency of the proposed care and treatment, the likely impact of the care and treatment on the individual's readiness and deployability, and the scope of the human and functional support network needed to support the individual.
- (3) In consultation with the Service member, formally advise the commander when the Service member's gender transition is complete and recommend to the commander a time at which the Service member's gender marker may be changed in DEERS.
- (4) Provide the Service member with medically necessary care and treatment after the Service member's gender marker has been changed in DEERS.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

c. Commander's Role.

The Service member's commander will:

- (1) Review the Service member's request to transition gender. Approves the timing and oversees, as appropriate, a transition process that:
- (a) Complies with DoD, Military Department, and Service regulations, policies, and guidance.
- (b) Considers the individual facts and circumstances presented by the Service member.
- (c) Maintains military readiness by minimizing impacts to the mission (including deployment, operational, training and exercise schedules, and critical skills availability), as well as to the morale, welfare, good order, and discipline of the unit.
 - (d) Is consistent with the medical treatment plan.
 - (e) Incorporates consideration of other factors, as appropriate.
- (2) Coordinate with the military medical provider regarding any medical care or treatment provided to the Service member and any medical issues that arise in the course of a Service member's gender transition.
- (3) Consult, as necessary, with the SCCC about service by transgender Service members and gender transition in the military; the execution of DoD, Military Department, and Military Service policies and procedures; and assessment of the means and timing of any proposed medical care or treatment.

d. Role of the Military Department and the USCG.

The Military Departments and USCG will:

- (1) Establish policies and procedures in accordance with this issuance, outlining the actions a commander may take to minimize impacts to the mission and ensure continued unit readiness in the event a transitioning individual is unable to meet standards or requires an ETP during a period of gender transition. Such policies and procedures may address the means and timing of transition, procedures for responding to a request for an ETP before the change of a Service member's gender marker in DEERS, appropriate duty statuses, and tools for addressing any inability to serve throughout the gender transition process. Any such actions available to the commander will consider and balance the needs of the individual and the needs of the command in a manner comparable to the actions available to the commander in addressing comparable Service members' circumstances unrelated to gender transition. Such actions may include:
- (a) Adjustments to the date the Service member's gender transition, or any component of the transition process, will begin.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

(b) Advising the Service member of the availability of options for extended leave status or participation in other voluntary absence programs during the transition process.

- (c) Arrangements for the transfer of the Service member to another organization, command, location, or duty status (e.g., Individual Ready Reserve), as appropriate, during the transition process.
- (d) ETPs associated with changes in the Service member's physical appearance and body composition during gender transition, such as accommodations in the application of standards for uniforms and grooming, BCA, PRT, and MPDATP participation.
- (e) Establishment of, or adjustment to, local policies on the use of berthing, bathroom, and shower facilities subject to regulation by the military during the transition process.
- (f) Referral, as appropriate, for a determination of fitness in the Integrated Disability Evaluation System in accordance with DoDI 1332.18 or the USCG Physical Disability Evaluation System, pursuant to Commandant Instruction M1850.2 (series).
- (2) Establish policies and procedures, consistent with this issuance, whereby a Service member's gender marker will be changed in DEERS based on a determination by the military medical provider that the Service member's gender transition is complete; receipt of written approval from the commander, issued in consultation with the Service member; and documentation indicating gender change provided by the Service member. Such documentation is limited to:
- (a) A certified true copy of a State birth certificate reflecting the Service member's self-identified gender;
- (b) A certified true copy of a court order reflecting the Service member's selfidentified gender; or
 - (c) A United States passport reflecting the Service member's self-identified gender.
 - (3) When the Service member's gender marker in DEERS is changed:
- (a) Apply uniform standards, grooming standards, BCA standards, PRT standards, MPDATP standards, and other standards applied with consideration of the Service member's gender, applicable to the Service member's gender as reflected in DEERS.
- (b) As to facilities subject to regulation by the military, direct the use of berthing, bathroom, and shower facilities according to the Service member's gender marker as reflected in DEERS.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

3.4. GENDER TRANSITION APPROVAL PROCESS.

a. A Service member on active duty who receives a diagnosis from a military medical provider for which gender transition is medically necessary may, in consultation with the military medical provider, request that the commander approve:

- (1) The timing of medical treatment associated with gender transition;
- (2) An ETP associated with gender transition, pursuant to Paragraphs 3.2.d., 3.2.f., or 3.3.d. of this issuance; or
 - (3) A change to the Service member's gender marker in DEERS.
- b. The commander, informed by the recommendations of the military medical provider, the SCCC, and others, as appropriate, will respond to the request within a framework that ensures readiness by minimizing impacts to the mission (including deployment, operational, training, exercise schedules, and critical skills availability), as well as to the morale, welfare, good order, and discipline of the command.
 - c. Consistent with applicable law, regulation, and policy, the commander will:
- (1) Comply with the provisions of this issuance and with Military Department and Service regulations, policies, and guidance, and consult with the SCCC.
- (2) Promptly respond to any request for medical care, as identified by the military medical provider, and require such care is provided consistent with applicable regulations.
- (3) Respond to any request for medical treatment or an ETP associated with gender transition as soon as practicable, but not later than 90 calendar days after receiving a request determined to be complete in accordance with the provisions of this issuance and applicable Military Department and Service regulations, policies, and guidance. The response will be in writing; will include notice of any actions taken by the commander in accordance with applicable regulations, policies, and guidance and the provisions of this issuance; and will be provided to both the Service member and their military medical provider. The commander will return any request that is determined to be incomplete to the Service member with written notice of the deficiencies identified as soon as practicable, but not later than 30 calendar days after receipt.
- (4) At any time before the change of the Service member's gender marker in DEERS, the commander, in consultation with the Service member and a military health care provider, may modify a previously approved approach to, or an ETP associated with, gender transition. A determination that modification is necessary and appropriate will be made in accordance with and upon review and consideration of the procedures and factors set forth in Paragraph 3.3.c. of this issuance. Written notice of such modification will be provided to the Service member pursuant to procedures established by the Military Department or Military Service, and may include options as set forth in Paragraph 3.3.d. of this issuance.
- (5) The commander will approve, in writing, the change of a Service member's gender marker in DEERS, after receipt of the recommendation of the military medical provider that the

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

Service member's gender marker be changed and receipt of the requisite documentation from the Service member. Upon submission of the commander's written approval to the appropriate personnel servicing activity, the change in the Service member's gender marker will be entered in the appropriate Service database, transmitted to the Defense Manpower Data Center, and updated in DEERS.

- d. As authorized by applicable Military Department and Service regulations, policies, and guidance implementing this issuance, a Service member may request review by a senior officer in the chain of command of a subordinate commander's decision with regard to any request pursuant to this issuance and any later modifications to that decision.
- e. A Service member who has completed a gender transition but has not resolved the gender dysphoria should consult with their military medical provider and commander. If a return to their previous gender is medically required, the Service member is to use the procedures outlined in Paragraph 3.4. of this issuance.

3.5. CONSIDERATIONS ASSOCIATED WITH RC PERSONNEL.

Excepting only those special considerations set forth in Paragraph 3.5. of this issuance, RC personnel are subject to all policies and procedures applicable to AC Service members as set forth in this issuance and in applicable Military Department and Military Service regulations, policies, and guidance implementing this issuance.

a. Gender Transition Approach.

All RC Service members (except Selected Reserve full-time support personnel) identifying as transgender individuals will submit to and coordinate with their chain of command evidence of a medical evaluation that includes a medical treatment plan. Selected Reserve full-time support personnel will follow the gender transition approval process set forth in Paragraph 3.4. of this issuance.

b. Diagnosis and Medical Treatment Plans.

A diagnosis established by a civilian medical provider will be subject to review and validation by a military medical provider pursuant to applicable Military Department and Military Service regulations, policies, and guidance. A treatment plan established by a civilian medical provider will be subject to review by a military medical provider and the military medical provider will validate any associated duty limitations pursuant to applicable Military Department and Military Service regulations, policies, and guidance.

c. Selected Reserve Drilling Member Participation.

To the greatest extent possible, commanders and Service members will address periods of non-availability for any period of military duty, paid or unpaid, during the Service member's gender transition with a view to mitigating unsatisfactory participation. In accordance with DoDI 1215.13, such mitigation strategies may include:

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

- (1) Rescheduled training;
- (2) Authorized absences; or
- (3) Alternate training.

d. Delayed Training Program (DTP).

Recruiters and commanders must advise DTP personnel of limitations resulting from being non-duty qualified. As appropriate, Service members in the DTP may be subject to the provisions of Paragraph 3.6. of this issuance.

e. Split Option Training.

When authorized by the Military Department or Military Service concerned, Service members who elect to complete basic and specialty training over two non-consecutive periods may be subject to the provisions of Paragraph 3.6. of this issuance.

3.6. CONSIDERATIONS ASSOCIATED WITH THE FIRST TERM OF SERVICE.

- a. A blanket prohibition on gender transition during a Service member's first term of service is not permissible. However, the All-Volunteer Force readiness model may be taken into consideration by a commander in evaluating a request for medical care or treatment or an ETP associated with gender transition during a Service member's first term of service. Any other facts and circumstances related to an individual Service member that impact that model will be considered by the commander as set forth in this issuance and implementing Military Department and Service regulations, policies, and guidance.
- b. The following policies and procedures apply to Service members during the first term of service and will be applied to Service members with a diagnosis indicating that gender transition is medically necessary in the same manner, and to the same extent, as to Service members with other medical conditions that have a comparable impact on the Service member's ability to serve:
- (1) A Service member is subject to separation in an entry-level status during the period of initial training in accordance with DoDI 1332.14, based on a medical condition that impairs the Service member's ability to complete such training.
- (2) An individual participant is subject to placement on medical leave of absence or medical disenrollment from the Reserve Officers' Training Corps in accordance with DoDI 1215.08 or from a Military Service Academy in accordance with DoDI 1322.22, based on a medical condition that impairs the individual's ability to complete such training or to access into the Military Services.
- (3) A Service member is subject to administrative separation for a fraudulent or erroneous enlistment or induction when warranted and in accordance with DoDI 1332.14, based on any deliberate material misrepresentation, omission, or concealment of a fact, including a

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

medical condition, that if known at the time of enlistment, induction, or entry into a period of military service, might have resulted in rejection.

(4) If a Service member requests non-urgent medical treatment or an ETP associated with gender transition during the first term of service, including during periods of initial entry training in excess of 180 calendar days, the commander may give the factors set forth in Paragraph 3.6.a. of this issuance significant weight in considering and balancing the individual need associated with the request and the needs of the command, in determining when such treatment, or whether such ETP may commence in accordance with Paragraphs 3.2.d, 3.2.f., and 3.3.d. of this issuance.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

SECTION 4: ADDITIONAL POLICY GUIDANCE

4.1. EQUAL OPPORTUNITY.

The DoD and the USCG provide equal opportunity to all Service members in an environment free from harassment and discrimination on the basis of race, color, national origin, religion, sex, gender identity, or sexual orientation, pursuant to DoDI 1350.02.

4.2. PROTECTION OF PII AND PHI.

- a. The Military Departments and the USCG will:
- (1) In cases in which there is a need to collect, use, maintain, or disseminate PII in furtherance of this issuance or Military Department and Military Service regulations, policies, or guidance, protect against unwarranted invasions of personal privacy and the unauthorized disclosure of such PII in accordance with Section 552a of Title 5, United States Code, also known as the Privacy Act of 1974, as amended; DoDI 5400.11; and DoD 5400.11-R.
- (2) Maintain such PII so as to protect individuals' rights, consistent with Federal law, regulation, and policy.
 - b. Disclosure of PHI will be consistent with DoDI 6025.18 and DoDI 6490.08.

4.3. PERSONAL PRIVACY CONSIDERATIONS.

A commander may employ reasonable measures to respect the privacy interests of Service members. Commanders are encouraged to consult with the Service member and SCCC when employing such measures.

4.4. ASSESSMENT AND OVERSIGHT OF COMPLIANCE.

- a. The Secretaries of the Military Departments and the Commandant, USCG will implement processes for the assessment and oversight of compliance with DoD, Military Department, and Military Service policies and procedures applicable to service by transgender persons.
- b. Beginning in fiscal year 2022 and at least every 3 years thereafter, the Secretaries of the Military Departments and the Commandant, USCG will direct a special inspection by the Service Inspector General or another appropriate auditing agency to ensure compliance with this issuance and implementing Military Department, Military Service or USCG regulations, policies, and guidance. Such reports will be endorsed and provided by the Secretary concerned to the USD(P&R) within 3 months of completion. The directing official will review the report of inspection for purposes of assessing and overseeing compliance; identifying compliance deficiencies, if any; timely initiating corrective action, as appropriate; and deriving best practices and lessons learned.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

- c. Any questions on gender identity in DoD cross-component assessment of Service members (e.g., surveys, focus groups interviews) must be approved by the USD(P&R) via the Department of Defense Human Resources Activity. The Secretaries of the Military Departments and the Commandant, USCG will implement processes for the approval of these questions for assessments containing these items administrated solely within their components. USD(P&R) approval is not required when transgender-related data:
- (1) Is being collected for the limited purpose of survey-based prevention research to inform primary prevention as defined in DoDI 6400.09.
 - (2) Collection conforms with DoDI 6400.11, Paragraph 5.3(c)(1)-(5).
- (3) Uses DoD-approved item language in accordance with Paragraph 5.3.d. of DoDI 6400.11.
 - (4) Follows policies outlined in DoDIs 8910.01, 1100.13, and 3216.02.
- d. Gender identity is a personal and private matter. DoD Components, including the Military Departments and Services, require written approval from the USD(P&R) to collect transgender and transgender related data or publicly release such data. USD(P&R) approval is not required when transgender-related data meets the conditions in Paragraph 4.4.c. Applicable privacy and human subject procedures should be followed to ensure appropriate safeguards are in place when conducting prevention research.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

GLOSSARY

G.1. ACRONYMS.

ACRONYM	MEANING	
AC	Active Component	
BCA	body composition assessment	
DEERS DHA DoDI DSM-5	Defense Enrollment Eligibility Reporting System Defense Health Agency DoD instruction American Psychiatric Association's Diagnostic and Statistical	
DTP	Manual of Mental Disorders: Fifth Edition Delayed Training Program	
ЕТР	exception to policy	
HIPAA	Health Insurance Portability and Accountability Act	
MPDATP MTF	Military Personnel Drug Abuse Testing Program military medical treatment facility	
PHI PII PRT	protected health information personally identifiable information physical readiness testing	
RC RLE ROTC	Reserve Component real life experience Reserve Officer Training Corps	
SCCC	Service Central Coordination Cell	
TRICARE	Military Health Care	
USCG USD(P&R)	United States Coast Guard Under Secretary of Defense for Personnel and Readiness	

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

G.2. DEFINITIONS.

These terms and their definitions are for the purpose of this issuance.

TERM	DEFINITION
cross-sex hormone therapy	The use of feminizing hormones in an individual assigned male at birth based on traditional biological indicators or the use of masculinizing hormones in an individual assigned female at birth. A common medical treatment associated with gender transition.
DTP	A program established by the Secretary of the Army to provide a personnel accounting category for members of the Army Selected Reserve to be used for categorizing members of the Selected Reserve who have not completed the minimum training required for deployment or who are otherwise not available for deployment.
gender dysphoria	A marked incongruence between one's experienced or expressed gender and assigned gender of at least 6 months' duration, as manifested by conditions specified in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders: Fifth Edition (DSM-5), page 452, which is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
gender identity	An individual's internal or personal sense of gender, which may or may not match the individual's biological sex.
gender marker	Data element in DEERS that identifies a Service member's gender. Service members are expected to adhere to all military standards associated with their gender marker in DEERS and use military berthing, bathroom, and shower facilities in accordance with the DEERS gender marker.
gender transition is complete	A Service member has completed the medical care identified or approved by a military medical provider in a documented medical treatment plan as necessary to achieve stability in the self-identified gender.
gender transition process	Gender transition in the military begins when a Service member receives a diagnosis from a military medical provider indicating the Service member's gender transition is medically necessary, and concludes when the Service member's gender marker in DEERS is changed and the Service member is recognized in the self-identified gender.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

TERM DEFINITION

human and functional support network

Support network for a Service member that may be informal (e.g., friends, family, co-workers, social media.) or formal (e.g., medical professionals, counselors, clergy).

medically necessary

Health-care services or supplies necessary to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms, and that meet accepted standards of medicine.

mental health provider

A medical provider who is licensed, credentialed, and experienced in the diagnosis and treatment of mental health conditions and is privileged at a Military MTF (in the direct care system). Private care sector civilian TRICARE authorized mental health providers may be involved in a specific Active Duty Service member's care. These providers are credentialed through the managed care support contractors.

military medical provider

Any military, government service, or contract civilian health care professional who, in accordance with regulations of a Military Department or DHA, is credentialed and granted clinical practice privileges to provide health care services within the provider's scope of practice in a Military MTF.

non-urgent medical treatment

The care required to diagnose and treat problems that are not life or limb threatening or that do not require immediate attention.

PHI

Individually identifiable health information (as defined in the HIPAA Privacy Rule) that, except as provided in this issuance, is transmitted or maintained by electronic or any other form or medium. PHI excludes individually identifiable health information in employment records held by a DoD covered entity in its role as employer. Information that has been de-identified in accordance with the HIPAA Privacy Rule is not PHI.

PII

Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual. Defined in OMB Circular No. A-130.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

TERM DEFINITION

RLE The phase in the gender transition process during which the

individual begins living socially in the gender role consistent with their self-identified gender. RLE may or may not be preceded by the commencement of cross-sex hormone therapy, depending on the medical treatment associated with the individual Service member, cadet, or midshipman's gender transition. The RLE phase is also a necessary precursor to certain medical procedures, including gender transition surgery. RLE generally encompasses dressing in the new gender, as well as using self-identified gender berthing, bathroom, and shower facilities.

bertining, bathroom, and shower facilities.

SCCC Service-level cell of experts created to provide multi-disciplinary

(e.g., medical, legal) advice and assistance to commanders regarding service by transgender Service members, cadets, or

midshipmen and gender transition in the military.

self-identified gender The gender with which an individual identifies.

stable in the selfidentified gender

The absence of clinically significant distress or impairment in social, occupational, or other important areas of functioning

associated with a marked incongruence between an individual's experienced or expressed gender and the individual's biological sex. Continuing medical care including, but not limited to, cross-sex hormone therapy may be required to maintain a state of

stability.

transgender Service Service member who has received a medical diagnosis indicating that gender transition is medically necessary, including any

Service member who intends to begin transition, is undergoing transition, or has completed transition and is stable in the self-

identified gender.

transition Period of time when individuals change from the gender role

associated with their sex assigned at birth to a different gender role. For many people, this involves learning how to live socially in another gender role. For others, this means finding a gender

role and expression that are most comfortable for them. Transition may or may not include feminization or

masculinization of the body through cross-sex hormone therapy

or other medical procedures. The nature and duration of

transition are variable and individualized.

> DoDI 1300.28, April 30, 2021 Change 1, December 20, 2022

REFERENCES

- American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders: Fifth Edition, May 18, 2013
- Commandant Instruction M1850.2D, "Physical Disability Evaluation System," May 19, 2006
- DoD 5400.11-R, "Department of Defense Privacy Program," May 14, 2007
- DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
- DoD Instruction 1100.13, "DoD Surveys," January 15, 2015, as amended
- DoD Instruction 1215.08, "Senior Reserve Officers' Training Corps (ROTC) Programs," January 19, 2017, as amended
- DoD Instruction 1215.13, "Ready Reserve Member Participation Policy," May 5, 2015
- DoD Instruction 1322.22, "Service Academies," September 24, 2015
- DoD Instruction 1332.14, "Enlisted Administrative Separations," January 27, 2014, as amended
- DoD Instruction 1332.18, "Disability Evaluation System," November 10, 2022
- DoD Instruction 1350.02, "DoD Military Equal Opportunity Program," September 4, 2020, as amended
- DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research," April 15, 2020, as amended
- DoD Instruction 5400.11, "DoD Privacy and Civil Liberties Programs," January 29, 2019, as amended
- DoD Instruction 6025.18, "Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Compliance in DoD Health Care Programs," March 13, 2019
- DoD Instruction 6025.19, "Individual Medical Readiness Program," July 13, 2022
- DoD Instruction 6400.11, "DoD Integrated Primary Prevention Policy for Prevention Workforce and Military Leaders," December 20, 2022
- DoD Instruction 6400.09, "DoD Policy on Integrated Primary Prevention of Self-Directed Harm and Prohibited Abuse or Harm," September 11, 2020
- DoD Instruction 6490.08, "Command Notification Requirements to Dispel Stigma in Providing Mental Health Care to Service Members", August 17, 2011
- DoD Instruction 8910.01, "DoD Implementation of the Paperwork Reduction Act," December 5, 2022
- Office of Management and Budget Circular No. A-130, "Managing Information as a Strategic Resource," July 28, 2016
- United States Code, Title 5, Section 552a (also known as the "Privacy Act of 1974,"), as amended

Document: 78-2 Case: 24-1714 Page: 91 Filed: 10/31/2024

DOD Revises Transgender Policies to Align With White House

March 31, 2021 | By Terri Moon Cronk, DOD News

You have accessed part of a historical collection on defense gov. Some of the information contained within may be outdated and links may not function. Please contact the <u>DOD Webmaster</u> with any questions.

Today is International Transgender Day of Visibility, and the Defense Department proudly recognizes transgender and gender non-conforming people and their continued struggle for equality, security and dignity, Pentagon Press Secretary John F. Kirby said.

"There is no place for violence and discrimination on the basis of sexual orientation, gender identity, or expression or sex characteristics," the press secretary said in a Pentagon news briefing today.

The DOD, along with its partners across the nation, will lead by example in the cause of advancing the human rights of LGBTIQ people around the world, he noted. LGBTIQ stands for lesbian, gay, bisexual, transgender, intersex and questioning individuals.

In January, President Joe Biden issued two executive orders that impact DOD transgender individuals: EO 1398, "Preventing And Combating Discrimination On The Basis Of Gender Identity Or Sexual Orientation," and EO 14004, "Enabling All Qualified Americans To Serve Their Country In Uniform."

Case: 24-1714 Document: 78-2 Page: 92 Filed: 10/31/2024 "Today, the department is announcing the publication of revised editions of these two instructions," Kirby said. The revised policies in these instructions restore the DOD's original 2016 policies regarding transgender service. Specifically, they prohibit discrimination on the basis of gender identity or an individual's identification as transgender. They also provide a means to access into the military in one's self-identify gender, provided all appropriate standards are met.

The editions provide a path for those in service for medical treatment, gender transition and recognition in one's self-identify gender, and they seek to protect the privacy of all service members and to treat them with dignity and respect at all times, he said.

The policies will be effective in 30 days to give the military services time to update service-level policies and provide guidance to commanders, service members, medical professionals and other communities of practice as appropriate during this period, Kirby added.



The department's interim guidance issued on January 29 remains in effect, he noted.

Case: 24-1714 Document: 78-2 Page: 93 Filed: 10/31/2024 "[Secretary of Defense Lloyd J. Austin III] strongly believes the all-volunteer force thrives when it is composed of diverse Americans who can meet the high standards for military service in an inclusive force that ... strengthens our national security posture," Kirby said.

Quoting Austin further, Kirby said, "The United States armed forces are in the business of defending our fellow citizens from our enemies, foreign and domestic. I believe we accomplish that mission more effectively when we represent all our fellow citizens."

"I also believe we should avail ourselves of the best possible talent in our population, regardless of gender identity. We would be rendering ourselves less fit to the task if we excluded from our ranks people who meet our standards and who have the skills and devotion to serve in uniform. This is the right thing to do. It is also the smart thing to do," Kirby said, quoting Austin.

Stephanie Miller, the DOD's military accession policy director, said department policy prohibits the discrimination on the basis of transgender status or gender identity. "That way, we try to protect the privacy of individuals," she said.



Document: 78-2 Page: 94 Case: 24-1714 Filed: 10/31/2024 "But a subset of the transgender population are those who have been medically diagnosed with gender dysphoria, and may be seeking or have completed medical care," she said. Based on that subset, she added, those who have been diagnosed and are seeking medical care total about 2,200 transgender people in the military ranks.

Miller said the DOD will provide medically necessary care to each individual member as prescribed in their medical treatment plan, which will be looked at on a case-by-case basis. "It's certainly determined with their medical provider, and it runs the gamut in terms of individuals who may only seek cross-sex hormone therapy, versus those who may pursue a surgical intervention, she explained.

Of the policies the DOD has published today, one is specific to medical accession standards, Miller said.

"Transgender applicants will certainly need to meet all other medical standards to include those standards that may be associated specifically with cross-sex hormone therapy, a previous diagnosis of gender dysphoria, or any form of surgical intervention," she said. "So, there are specific standards associated with those medical conditions or medical surgical interventions, but certainly individuals have to meet all other qualifying standards in that instruction."

Hosted by Defense Media Activity - WEB.mil

Case: 24-1714rmy TDocument: 778:20n caPage: 25r Traffiled: \$10/31/2024com



7/23/24, 8:31 PM



Sign up

-48% Marine Corps Coast Guard Space Force Navy Air Force

Military Podcasts Opinion Videos

Army To Provide Gender Transition Care, Surgeries for Transgender Soldiers











In this July 26, 2017 photo, people with the Human Rights Campaign hold up "equality flags" during an event on Capitol Hill in Washington, in support of transgender members of the military (AP Photo/Jacquelyn Martin)

Military.com | By Steve Beynon Published June 28, 2021

Transgender soldiers can openly serve in the Army and the force will provide hormone theropy, mental health care and surgeries they might require, according to a force-wide memo issued out last week.

"This directive supersedes all previous guidance," Maj. Gen. Douglas Stitt, director of the Army G-1 Military Personnel Management Office, told reporters at a June 24 news conference. "The Army is open to all who can meet the standards. No otherwise qualified soldiers may be discharged or denied service, solely on the basis of gender identity."





government fares. Learn more.

A soldier's gender identity will no longer be a cause for involuntary separation, denied reenlistment or other adverse action, according to the memo. The Army's new policy follows President Joe Biden's executive order on his first week in office in January repealing a Trump-era ban on transgender troops.

Read Next: Eddie Gallagher Vs. the World: After War Crimes Trial, Notorious SEAL Is Out to Settle Scores

To qualify for gender-transition care, soldiers have to be diagnosed with gender dysphoria. According to the American Physicatric Assosication, gender dysphoria refers to psychological distress resulting from an individual's biological sex conflicting with their identity.



Treatment from the Army will consist of four elements: "hormones, psychotherapy, real-life experience, and surgical intervention," Col. Deidra Briggs-Anthony, assistant deputy of health affairs for manpower and reserve affairs explained. But not all soldiers will require all four components for their transition.

"That timeline can vary, case by case. Some may need weeks, others could [need] months," Briggs-Anthony said. "The plan made by health care providers will be





placed on a medical profile.

According to the memo, the "real-life experience" is a "necessary precursor" to genderrelated surgeries. The real-life experience phase "generally encompasses dressing in the new gender and using self-identified gender bathroom and showering facilities."

Once the soldier feels stable and their transition is complete, their self-identified gender will be reflected in Army personnel records. Once that change is final, all physical standards and requirements for that given gender will apply, according to the memo. While the Army's previous fitness test had a dramatic difference in standards between men and women, it is unclear if the new test will incorporate gender-specific standards as leaders continue to tweak it.

Transgender candidates previously had to serve in their biological sex and prove they have been mentally and physically stable for 36 months before enlisting or commissioning in the Army. Under the new policy, new recruits can serve in their self-identified gender and only have to demonstrate 18 prior months of stability. That timeline can also be waived in certain circumstances, according to the new policy.

Applicants to join the Army must have a U.S. passport or certified copy of a court order reflecting their self-identified gender.

It is unclear how many transgender troops there are. Defense Department data shows there are 726 soldiers serving in the Army who have been diagnosed with gender dysphoria, the most out of all the branches. DoD shos 576 transgender service members in the Navy, 449 in the <u>Air Force</u> and 141 in the <u>Marine Corps</u>, but the data could skew low given the likelihood of additional troops who never sought a formal diagnosis.

<u>Earlier this month, Military.com reported</u> the Pentagon has spent \$15 million in the past five years to treat 1,892 transgender troops, including \$11.5 million for psychotherapy and \$3.1 million for surgeries - a relative drop in the bucket compared to the mammoth \$35.6 billion for descretionary health care spending in the proposed 2022 budget.





The Army's policy follows the <u>Department of Veterans Affairs</u>' announcement that they too would provide gender confirmation surgery to transgender veterans.

"We're making these changes not only because they are the right thing to do, but because they can save lives," VA Secretary Denis McDonough said earlier this month. "When President Biden nominated me to lead the VA, he told me to fight like hell for our Vets. And when he said that, he meant all veterans."

- Steve Beynon can be reached at Steve.Beynon@military.com. Follow him on Twitter
 @StevenBeynon.
- -- Patricia Kime contributed to this report

Related: Here's How Much the Pentagon Has Spent So Far to Treat Transgender Troops

Related Topics: Military Headlines, Army, Transgender, Active Duty Benefits

Steve Beynon



Steve Beynon is a reporter for Military.com based out of the Washington, D.C., area whose detailed investigations have covered urgent issues impacting soldiers. He has an extensive background in covering senior military leadership conduct, the Pentagon's recruiting struggles and

extremist organizations. Read Full Bio

© Copyright 2024 Military.com. All rights reserved. This article may not be republished, rebroadcast, rewritten or otherwise distributed without written permission. To reprint or license this article or any content from Military.com, please submit your request here.

Sponsored Link: Save Big on Military Auto Insurance







Coast Guard Investigating Academy Official Who Threatened to Resign over its Handling of Sexual Assault Scandal



Former US Army Civilian Employee Sentenced to 15 Years for Stealing Nearly \$109 Million



Marine Corps Wants Rifle-Mounted Jammers, 'Buckshot-Like' Ammo to Help Grunts Counter Drones



Fort Wainwright Soldier Killed by Alleged Drunk Driver at Main Gate

Military News

- Investigations and Features
- Army
- Navy
- Air Force

- Marine Corps
- Coast Guard
- Space Force
- Military Opinion



67°F







Select Service

Army Marines Navy Air Force

National Guard Space Force Coast Guard Spouse

Login

Most Popular Military News







SID DIIIION DUUYEL SHURTIAN

The VA said it is working with the White House and Congress to address the budget shortfalls in a way that doesn't harm...



Commander at Eglin Air Force Base Fired from Job Days Before He Was Set to Leave Post



Volunteer or Voluntold: Marines Announce Special Duty Assignment Campaign for Active Reserves



Troops Will Start Getting Economic Hardship Bonuses This Month, Though Only \$20 on Average



Army Officer Gropes 16-Year-Old on Flight, Then Assaults Another Passenger, Feds Say



Save up to 90% on Temi

Big discount on Temu. Up to 90% off. Shop now.



Latest Benefits Info

- Servicemembers' Group Life Insurance (SGLI): What You Need to Know
- Using Your GI Bill For Graduate School
- GI Bill for College Students



View More

More Military Headlines



Coast Guard Investigating Academy Official Who Threatened to Resign over its Handling of Sexual Assault Scandal

Shannon Norenberg, the school's sexual assault response coordinator, is fighting a move to reassign her after she retracted...





Sign up

View More

Army

- Former US Army Civilian Employee Sentenced to 15 Years for Stealing Nearly \$109 Million
- Fort Wainwright Soldier Killed by Alleged Drunk Driver at Main Gate
- 3 Army Officials Punished After Investigation of Maine Reservist's Mass Shooting Finds Numerous Failures

View More

Air Force

- Commander at Eglin Air Force Base Fired from Job Days Before He Was Set to Leave Post
- Air Force Academy Believes Dorm Remodel Could Cost Almost \$600 Million
- National Guard Chief Warns of 'Unintended Consequences' of Transferring Air Guard Units to Space Force

View More

Navy

- Michigan, Navy and Pentagon Announce Partnership to Train Workers for Defense Production
- Families Look Back on Legacy, Tragedy of Port Chicago Military Disaster After Sailors Exonerated
- Troops Will Start Getting Economic Hardship Bonuses This Month, Though Only \$20 on Average





Military Benefits Updates

- The Next Deadline for Backdated PACT Act Payments Is Coming Soon. Here's What You Need to Know
- VA Fertility Benefits for Military Veterans
- Virginia Veterans Rally the Troops, State Leaders in Support of Education Benefits

 View More	

Marine Corps

- Marine Corps Wants Rifle-Mounted Jammers, 'Buckshot-Like' Ammo to Help Grunts Counter Drones
- Volunteer or Voluntold: Marines Announce Special Duty Assignment Campaign for Active Reserves
- Troops Will Start Getting Economic Hardship Bonuses This Month, Though Only \$20 on Average

View More	

Coast Guard

- Coast Guard Investigating Academy Official Who Threatened to Resign over its Handling of Sexual Assault Scandal
- Disaster Response Training at RIMPAC in Hawaii Grows
- Coast Guard Rescue Swimmer Honored for Saving 3 Imperiled Sailors in Alaska

View More	
 View More	





- · 'Rabbids: Legends of the Multiverse' Adds Strategic Twists to a Tower Defense Game
- Navy SEAL Vet Jack Carr's First-Ever Nonfiction Book Traces the Roots of the Global War on Terror
- · Bob Newhart, Award-Winning Comedian, TV Legend and Army Veteran, Dies at 94





Search Military.com

 $GO \rightarrow$

NEWS BENEFITS

News Home Benefits Home

Army Military Pay and Money

Navy GI Bill

Air Force Veteran Health Care

Marine Corps Tricare

Coast Guard



Opinion Videos

VA eBenefits

VETERAN JOBS

Veteran Job Search

Military Skills Translator

Upload Your Resume

Veteran Employment Project

Vet Friendly Employers

Career Advice

MILITARY LIFE

Military Life Home

Money

Off Duty

Fitness

Military Trivia Game

Veterans Day

Spouse & Family

Deployment

Military History

DISCOUNTS

Discounts Home

Featured Discounts

Veterans Day Restaurant Discounts

Dining

Travel

Retail

Insurance

Services

Auto

Electronics

JOIN THE MILITARY

Join the Military Home

ASVAB

Contact a Recruiter

Military Fitness

Benefits

Military.com Network

All Force | Army | Goast Buard | Marine Corps | National Buard | Navy | Space Force





About Military.com

About Us & Press Room | Mobile Apps | RSS | Advertise with Us | Reprints & Permissions -Subscriptions | User Agreement | Privacy Policy | Your Privacy Choices

Need customer support?

Visit our Customer Support center for solutions or to contact us.

Customer Support

© 2024 Military Advantage

AdChoices D





FY2024 NDAA: TRICARE Coverage of Gender-Affirming Care

Updated January 4, 2024

Background

The Department of Defense (DOD) administers a statutory health entitlement (under Title 10, Chapter 55, of the *U.S. Code*), through the Military Health System (MHS). The MHS offers health care benefits and services through its TRICARE program to approximately 9.5 million beneficiaries composed of servicemembers, military retirees, and dependent family members. Congress often specifies certain TRICARE coverage parameters (e.g., how health care services may be delivered, and whether beneficiaries may be subject to cost-sharing requirements) through an annual National Defense Authorization Act (NDAA).

During ongoing deliberations on a FY2024 NDAA, Congress has expressed interest in TRICARE coverage policies for gender-affirming care. Defense Health Agency (DHA) Procedural Instruction 6025.21 defines gender-affirming care as "clinical services that support an individual's physical and [behavioral health] as they define, explore, and align with their gender identity." Gender-affirming care includes non-surgical care (e.g., hormone therapy and psychotherapy) and surgical care (e.g., gender-affirming surgery).

The TRICARE Policy Manual stipulates that "medically or psychologically necessary and appropriate medical care (as defined in 32 C.F.R. §199.2), including non-surgical treatments for [gender dysphoria], are covered [for all beneficiaries] when provided by a TRICARE-authorized provider." For hormone therapy, a beneficiary diagnosed with gender dysphoria must also meet the eligibility criteria outlined in the Endocrine Society's clinical practice guideline for treatment of gender dysphoria. Under 10 U.S.C. §1079(a)(11)), TRICARE is explicitly prohibited from covering gender-affirming *surgical* care for beneficiaries except to treat individuals with an intersex condition due to congenital malformations or chromosomal abnormalities.

This statutory prohibition applies only to health care services covered by the TRICARE program for beneficiaries; DOD may pay for gender-affirming surgical care through the Supplemental Health Care Program (SHCP) for "active duty members of the uniformed services." SHCP is authorized under 10 U.S.C. §1074(c), 32 C.F.R. §199.16, Health Affairs Policy 12-002, and the TRICARE Operations

Congressional Research Service

https://crsreports.congress.gov

IN12203

CRS INSIGHT
Prepared for Members and
Committees of Congress —

Case: 24-1714

Manual. The DHA Director may consider requests from the military services to use SHCP funds to "lawfully cover otherwise non-covered services for Service members in circumstances that will enable them to return to full duty/worldwide deployable status, or to reach their maximum rehabilitative potential." Typically, DHA uses SHCP to pay for non-covered services (e.g., certain emerging medical therapies and services, fertility services, or unique rehabilitative services).

Document: 78-2

DHA policy outlines the process for providing gender-affirming surgical care to an active duty servicemember diagnosed with gender dysphoria, which includes requirements for the servicemember to obtain endorsements from their respective transgender care team and their chain of command prior to being authorized care.

Table 1 lists the proposed and enacted gender-affirming care-related provisions included the House-passed (H.R. 2670), Senate-passed (S. 2226), and enacted (P.L. 118-31) versions of the FY2024 NDAA.

Enacted Legislation (P.L. 118-31) House-passed H.R. 2670 Senate-passed S. 2226 Section 640C would have prohibited an Not adopted. No similar provision. **Exceptional Family Member Program** from providing "gender transition procedures" or providing referrals for "gender transition services" to a minor dependent child. The provision would also prohibit the approval of a change of duty station due to a minor dependent child having a lack of access to gender transition services. Section 717 would have amended Title No similar provision. Not adopted.

Table 1. FY2024 NDAA Legislative Proposals

Source: CRS analysis of legislation on Congress.gov.

Discussion

beneficiaries.

10, Chapter 55, of the U.S. Code, to prohibit DOD from providing or paying for gender-affirming surgical care and hormone treatment for all

The number of TRICARE beneficiaries who identify as transgender and have sought or received gender-affirming care is unclear, though some estimates of transgender servicemembers have been reported over the past several years. In 2016, the RAND Corporation estimated that approximately 1,320 to 6,630 of the 1.3 million active duty servicemembers identified as transgender. The report also estimated the potential cost to expanding TRICARE coverage to include gender-affirming surgical care for active duty servicemembers, which ranged between \$2.4 million and \$8.4 million annually. Between January 1, 2016 and May 14, 2021, DOD reportedly spent approximately \$15 million to provide gender-affirming care (surgical and non-surgical care) to 1,892 servicemembers.

Congress continues to debate whether federal health programs, like TRICARE, should cover gender-affirming care and related support services. Certain observers argue that federal taxpayer funds should not be used to pay for gender-affirming care that they perceive as "costly and controversial" and that such care could impact a servicemember's ability to be "combat-ready" or "deployable." Other observers argue that there is a "growing consensus" among medical experts that gender-affirming care is medically necessary and that health payers should ensure coverage of these services.

Congressional Research Service

3

The House-passed bill included two related provisions that were not adopted in the enacted FY2024 NDAA. The SASC-reported bill had no similar provisions. Section 717 of the House-passed bill would have amended Title 10, Chapter 55, of the *U.S. Code*, by adding a new section that prohibits DOD from providing or paying for gender-affirming surgical care and hormone treatment used to treat gender dysphoria under TRICARE and SHCP.

In certain instances, a dependent family member diagnosed with a "current and chronic" mental health condition requiring "inpatient or intensive (i.e., greater than one visit monthly for more than 6 months) outpatient mental health service" may access additional family support services through the Exceptional Family Member Program (EFMP). Dependent family members diagnosed with gender dysphoria, as a mental health condition categorized by the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), could also be eligible to enroll in EFMP.

DOD policy also allows EFMP-enrolled servicemembers to request a reassignment to another duty station before meeting the minimum time-on-station requirement, and to be afforded certain housing flexibilities during their relocation to another duty station. Section 640C of the House-passed bill would have prohibited EFMP from providing or making referrals for a minor dependent child to obtain "gender transition procedures, including surgery or medication." The provision would have also prohibited the military services from approving a servicemember's request for early reassignment to another duty station due to a minor dependent child having lack of access to gender transition services.

Author Information

Bryce H. P. Mendez Specialist in Defense Health Care Policy

Disclaimer

This document was prepared by the Congressional Research Service (CRS). CRS serves as nonpartisan shared staff to congressional committees and Members of Congress. It operates solely at the behest of and under the direction of Congress. Information in a CRS Report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to Members of Congress in connection with CRS's institutional role. CRS Reports, as a work of the United States Government, are not subject to copyright protection in the United States. Any CRS Report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS Report may include copyrighted images or material from a third party, you may need to obtain the permission of the copyright holder if you wish to copy or otherwise use copyrighted material.

Donate



Sign up for our newsletter

Case: 24-1714

Military

Trans veterans were promised access to gender-affirming surgeries — but it never happened

The Transgender American Veterans Association filed a lawsuit on Thursday over the Department of Veterans Affairs' failure to act after years of inaction.

It's been three years since President
Joe Biden signed an executive order
overturning the Trump
administration's ban on transgender
people serving in the military. Months
later, the secretary of the U.S.
Department of Veterans Affairs (VA)
announced that the agency would
provide gender-confirmation surgery.

Mariel Padilla General Assignment Reporter



Published

January 25, 2024, 8:01 a.m. PT

But that change has not happened, so the Transgender American Veterans Association (TAVA) filed a lawsuit on Thursday against the VA over its failure to act.

ta Eshler, a transgender veteran and president of TAVA, said the Biden Donate stration had made promises without any concrete action, and transgender veterans feel like they are being "used for political showmanship."

"We're filing the lawsuit because we're kind of stuck," Eshler said. "We still haven't heard anything. Every time we've asked about the change, it's next week or the next week. We know it's on the desk of the secretary, but they haven't given us any reasons why it hasn't moved any further. We just want to know why. We want to build trust back."

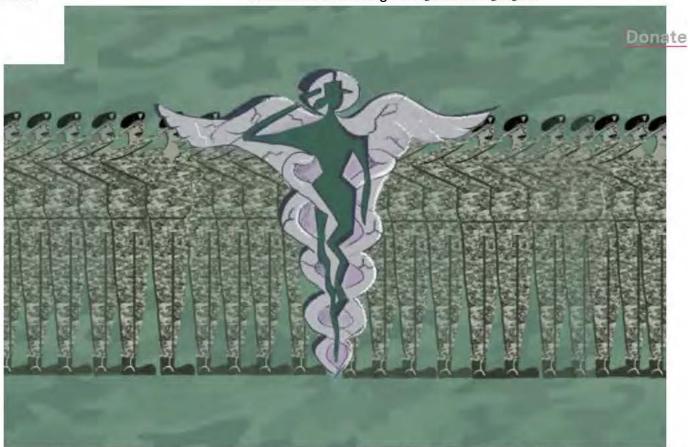
The lawsuit calls for the VA to respond within 30 days. When reached for comment, the administration said it "does not comment on potential or pending litigation."

In 2016, TAVA submitted a formal petition requesting that genderconfirmation surgeries be recognized as "medically necessary" and provided to veterans. The VA currently provides other non-surgical gender-affirming care, including hormone therapy, voice training, gender-affirming prosthetics, pre- and post-operative care and support groups.

Eshler said that transgender people serve in the military at higher rates than their cisgender counterparts, but are far less likely to use VA facilities for health care due to harassment, stigma and a lack of resources. Though data is incomplete, studies estimate that trans men and women are two to three times more likely to join the military. Yet, Eshler said only 6.25 percent of transgender veterans use the VA health care system.

More Like This

Case: 24-1714



Women and LGBTQ+ veterans say VA facilities 'weren't built with us in mind'

Veterans discharged under 'Don't Ask, Don't Tell' are still fighting for justice — and benefits

VA insurance won't cover IVF for LGBTQ+ and unmarried veterans

"We don't have trust in the VA," Eshler said. "They don't even follow their own directives. There's countless stories: the VA misgendering people, no consistency in care across facilities, no national line where they take or even track complaints."

Natalie Kastner, a Texas-based transgender veteran, said she could have died on March 5, 2022, because she felt like there were no other options for her: The VA did not provide gender-confirmation surgery, and civilian care would have cost about \$60,000 out-of-pocket. So she took matters into her own hands.

up, and I was feeling gender dysphoric," Kastner said. "I walked into hroom with a paring knife and a pair of scissors, laid myself in the Donate tub," and attempted to perform surgery on herself.

She cleaned up the bathroom and went back to bed, only to be woken up later by her cat. Seeing that she was still bleeding profusely, despite feeling no pain, Kastner said she drove herself to the closest emergency room, where it was discovered she had cut through an artery.

"I did this to fix my body," said Kastner, who served from 2006 to 2008 before she was honorably discharged due to a back fracture. "I didn't want to die. I have an ex-wife and two children that I care for deeply, and I never want to leave them like that. But that night, my gender dysphoria became too much, and I broke."

Transgender veterans are more at risk of suicide than the transgender community and the veteran community at large. Veterans already have a suicide rate more than 57 percent higher than civilians, according to the Centers for Disease Control and Prevention. And about 40 percent of transgender people in the United States attempt to take their own lives at least once in their life, compared to .07 percent of all adults. But transgender veterans are more than 20 times more likely than other veterans to experience "suicide-related events," according to a 2023 peer-reviewed study published in The Cureus Journal of Medical Science.

"Surgeries save lives," said Kastner, now 39 and a member of TAVA. "With access to the surgery, I would have waited. I would have had hope."

She emphasized the difference that would have made for her health – and why it matters to veterans.

"The VA says they will serve those who have served," Kastner said. "By not providing these surgeries, they're letting us die. How is that serving those who have served?"

sh this story

Case: 24-1714



Recommended for you



White House says it opposes gender-affirming surgery for minors



Ohio bill with gender-affirming care ban and trans sports restrictions heads to governor's desk



A Kansas Republican voted for a gender-affirming care ban. But then she flipped.



This Georgia county spent \$1 million to avoid paying for one employee's gender-affirming care

The 19th

The 19th is a 501(c)(3) tax-exempt organization. Our stories are free to republish in accordance with these guidelines.

PRESS

DONATE

Back to News

Black Veterans Project Supports Gender-Affirming Care



Case: 24-1714 Document: v782 ProjeRage: tts1de8ter-Affilled: c10/31/2024 7/23/24, 8:45 PM



Written by Published

Richard Brookshire

July 22, 2024

On April 15, 2024, the Transgender American Veterans Association (TAVA) filed a second federal lawsuit against the U.S. Department of Veterans Affairs (VA), challenging VA's denial of TAVA's 2016 rulemaking petition requesting gender-affirming surgery. VA's denial of TAVA's petition came after nearly eight years of no response—and nearly three years of Secretary McDonough publicly promising to provide the care it requested. TAVA's lawsuit contends that VA's denial of the petition's request for necessary medical care for transgender veterans violates the Administrative Procedure Act, the Constitution, and Section 1557 of the Affordable Care Act.

TAVA's lawsuit challenges VA's denial of its rulemaking petition, which maintains its refusal to provide gender-affirming surgery at VA. The lawsuit follows an earlier one filed by TAVA in January 2024, which sought a court order that VA formally respond to TAVA's 2016 rulemaking petition requesting gender-affirming surgery. In response, VA breached its repeated public promises to make gender-affirming surgery available by denying TAVA's petition.

In support of TAVA, Black Veterans Project is sharing relevant documents obtained through the Freedom of Information Act. (BVP FOIA Document)



Join the fight

First Name

Last Name

Phone

Case: 24-1714

Zip Code

Email

Submit

Black Veterans Project is not a service/benefit delivery organization nor a membership based organization. Please sign up if you would like to be added to our mailing list to receive our biannual newsletter or contact us with any questions or media requests.

STORYTELLING

Contact Us

RESEARCH

Email

TEAM

info@blackveteransproject.org

NEWS



Case: 24-1714 Document: v78.2 ProjeRage: tsl 20ter-Affilled: c1.0/31/2024

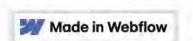
DONATE

7/23/24, 8:45 PM









Assistant Director, Reserve and Medical Manpower This email message is for the sole use of the intended recipient(s) and may contain information that is for official use only. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. ----Original Message----From: (b)(6) Sent: Wednesday, July 12, 2017 4:37 PM To (b)(6) Subject: FW: Follow up on AMSWG comments regarding DOD/VA discrepancy in treatment of TG conditions /disability (UNCLASSIFIED) ----Original Message----From: (b)(6) Sent: Wednesday, July 12, 2017 4:18 PM To: (b)(6) (b)(6)Subject; RE: Follow up on AMSWG comments regarding DOD/VA discrepancy in treatment of TG conditions /disability (UNCLASSIFIED) CLASSIFICATION: UNCLASSIFIED Classification: UNCLASSIFIED Caveats: NONE Folks. While I am pretty new to the interagency workings I see this as a very big problem. The two institutions should have identical definitions of medically necessary. If we disagree then outsiders will automatically view the medical decisions as being influenced by economics, politics, or personal belief systems and our credibility will be called into question. R (b)(6)----Original Message----From: (b)(6)

Document: 78-2

Case: 24-1714

Page: 121

Filed: 10/31/2024

Case: 24-1714 Document: 78-2 Page: 122 Filed: 10/31/2024 Sent: Wednesday, July 12, 2017 3:57 PM To: (b)(6) OSD OUSD P-R (US) Cc (b)(6) Subject: RE: Follow up on AMSWG comments regarding DOD/VA discrepancy in treatment of TG conditions /disability (UNCLASSIFIED) Yes(b)(6) that is correct. The DHA IPM team is drafting a policy document reflect what is medically necessary and what is considered cosmetic. There is a significant difference between the two agencies. Best. (b)(6)(b)(6)This email message is for the sole use of the intended recipient(s). Privacy Act of 1974 as Amended applies. This email may contain information that is protected IAW DoD 5400.11R and is For Official Use Only (FOUO) unless otherwise noted. Any unauthorized review, use, disclosure or distribution prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. ----Original Message----From: (b)(6) 2017 3:50 PM Sent: Wednesday, July 12. To (b)(6) Cc (b)(6)Subject: RE: Follow up on AMSWG comments regarding DOD/VA discrepancy in treatment of TG conditions /disability (UNCLASSIFIED) CLASSIFICATION: UNCLASSIFIED Sure, and (b)(6) correct me if I miss something. Just saw your email come in with the supporting documents, so thanks! The DOD will perform or cover surgeries associated with transition if they deemed medically necessary to treat the gender dysphoria. This may include hysterectomy, orchietomy, or mastectomy, which are all compensable. However, VA says they don't see these as compensable in this situation because

Page: 123 Case: 24-1714 Document: 78-2 Filed: 10/31/2024 they don't count them as medically necessary. This could create an adverse situation for the VA and DOD because it doesn't follow that the procedures are medically necessary in one system and not in the other. The documents on Martie's email provide additional background. Many thanks, (b)(6)----Original Message----From (b)(6) Sent: Wednesday, July 12, 2017 3:06 PM To: (b)(6) (b)(6)Cc: (b)(6) (b)(6)Subject: RE: Follow up on AMSWG comments regarding DOD/VA discrepancy in treatment of TG conditions /disability (UNCLASSIFIED) (b)(6) Can you remind me of the specifics that Martie provided during the meeting. Then I will voice it to the leadership to see which forum and venue the conversation gets directed towards (typically what happens). Very Respectfully, (b)(6)This email message is for the sole use of the intended recipient(s) and may contain information that is for official use only. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

----Original Message----From:(b)(6) Case: 24-1714 Document: 78-2 Page: 124 Filed: 10/31/2024

Sent: Wednesday, July 12, 2017 11:54 AM To: (b)(6)	
Ce: b)(6)	<u> </u>
Subject: Follow up on AMSWG comments regarding DO	OD/VA discrepancy in
treatment of TG conditions /disability (UNCLASSIFIED)	Annual Section of the Principle of the Control of the Section of t

CLASSIFICATION: UNCLASSIFIED

(b)(6)

Greetings! Great job shepherding our group through the discussion this morning.

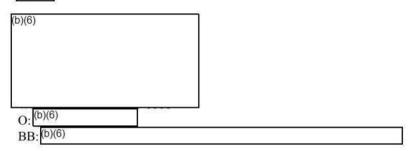
I had to step away for a farewell so am sending this note to follow up on the

topic of DOD and VA having seemingly different positions on the classification

of TG.

As Martie mentioned, this has the potential for significant impact. Do you have thoughts on what would be the best forum to address this? Many thanks!

(b)(6)



CLASSIFICATION: UNCLASSIFIED CLASSIFICATION: UNCLASSIFIED

Classification: UNCLASSIFIED

Caveats: NONE

CLASSIFICATION: UNCLASSIFIED

290 of 940

From: (b)(6)

To: Reynolds, Robert, VBAVACO

Subject: [EXTERNAL] RE: [Non-DoD Source] FW: Question -- VA Disability Rating/Compensation for Transgender Service

Members (UNCLASSIFIED)

Date: Friday, July 7, 2017 11:46:20 AM

Sir,

Thank you for allowing me to share my thoughts. I believe a point of discussion is the DoD position to provide medically necessary care for the treatment of gender dysphoria. The VA sees gender dysphoria as a pre-existing condition present from birth, thus surgical procedures are seen as elective.

Separating transgender Service members who've had sex reassignment procedures, done under the premises of being medically necessary, may raise the issue of not being compensated for such surgeries.

I look forward to further discussions.

Best,	_
(b)(6)	

(b)(6)			

This email message is for the sole use of the intended recipient(s). Privacy Act of 1974 as Amended applies. This email may contain information that is protected IAW DoD 5400.11R and is For Official Use Only (FOUO) unless otherwise noted. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

----Original Message----

From: Reynolds, Robert, VBAVACO [mailto:rob.reynolds@va.gov]

Sent: Friday, July 07, 2017 10:56 AM

To: (b)(6)

Subject: RE: [Non-DoD Source] FW: Question -- VA Disability

Rating/Compensation for Transgender Service Members (UNCLASSIFIED)

Nice to speak with you and will discuss further but still believe our position in this regard is this condition is something you are born with and not an injury, illness, or aggravation of a pre-existing condition that was aggravated beyond natural progression which happened as a result of military service.

Thanks,
Rob
Od datManage
Original Message From:(b)(6)
[mailto(b)(6)
Sent: Friday, July 07, 2017 9:18 AM
To: Reynolds, Robert, VBAVACO
Subject: [EXTERNAL] FW: [Non-DoD Source] FW: Question VA Disability
Rating/Compensation for Transgender Service Members (UNCLASSIFIED)
Good morning Mr. Reynolds/Rob,
SERVE NEWSCOOL CO. COMMENT OF THE COMMENTS AND ADMINISTRATION OF THE COMMENTS AND ADMI
Would I be out of line in asking you a question about VBA disability
rating/compensation? I want to be careful about jumping any chains.
Thanks,
0)(6)
(b)(6)
This email message is for the sole use of the intended recipient(s).
Privacy Act of 1974 as Amended applies. This email may contain information
that is protected IAW DoD 5400.11R and is For Official Use Only (FOUO)
unless otherwise noted. Any unauthorized review, use, disclosure or
distribution is prohibited. If you are not the intended recipient, please
contact the sender by reply email and destroy all copies of the original
message.
0.1.1.17
Original Message From (b)(6)
Sout Thursday, July 06, 2017 5-19 DM
Sent: Thursday, July 06, 2017 5:18 PM To: (b)(6)
(b)(6)
ı

Subject: FW: [Non-DoD Source] FW: Question -- VA Disability Rating/Compensation for Transgender Service Members (UNCLASSIFIED)

FYI Please share with other members of the TGWG I miss																		
	cod	mic	W/	CV	T	tha	of	ore	mb	1226	hor	at	with	ara	ch	anca	D	EVI

(b)(6)
Original Message
From: (b)(6) Sent: Thursday, July 06, 2017 4:46 PM To: (b)(6)
Subject: FW: [Non-DoD Source] FW: Question VA Disability Rating/Compensation for Transgender Service Members (UNCLASSIFIED)
For our files.
(b)(6)
Original Message From (b)(6) Sent: Thursday, July 06, 2017 4:40 PM To (b)(6) Cc Subject: FW: [Non-DoD Source] FW: Question VA Disability Rating/Compensation for Transgender Service Members (UNCLASSIFIED)
CLASSIFICATION: UNCLASSIFIED
Ma'am
Attached is (b)(6) response regarding VA's guidance for gender reassignment surgeries. He reached out to Rob Reynolds who confirmed VA considers these procedures as elective and does not award disability compensation unless there are complications as a result of the surgery while in service(i.e., painful scars, pelvic adhesions), service-connection could be established for these conditions.
Regarding pre-existing mental conditions, service-connection may be granted if the evidence established the condition was aggravated beyond its natural progression during active military service.
(b)(6) also provided VA guidance on gender dysphoria and providing health care for transgender and intersex Veterans.
R/
(b)(6)
From: (b)(6) Sent: Thursday, July 6, 2017 3:29 PM
To: (b)(6) Ce:
(b)(6)

Subject: [Non-DoD Source] FW: Question -- VA Disability Rating/Compensation for Transgender Service Members (UNCLASSIFIED)

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

(b)(6)

(b)(6)

I'm attaching several documents to assist in your work on transgender policy. VHA Directive 2013-003 covers providing healthcare for transgender and intersex veterans the second is VBA's paper on the topic. Rob Reynolds sent me a note that states "VBA does not view gender dysphoria and any elective surgical procedures relating to this condition as service-connected disabilities. However, if the Veteran experiences any complications as a result of the surgery while in service(i.e., painful scars, pelvic adhesions), service-connection could be established for these conditions. Regarding pre-existing mental conditions, service-connection may be granted if the evidence established the condition was aggravated beyond its natural progression during active military service."

Let me know if there is anything else you might need.

Best, (b)(6)	
(b)(6)	
(b)(6)	
Office of Policy and Interagency	Collaboration
Office of Enterprise Integration	
Department of Veterans Affairs	
Work: (b)(6)	
Mobile	
Original Message	
From(b)(6)	
Sent: Monday, July 3, 2017 12:54	4 PM
To: (b)(6)	@va.gov>
Ce: (b)(6)	@va.gov>
Subject: Question VA Disabili	ty Rating/Compensation for Transgender
Service Members (UNCLASSIF)	[프] , '무슨 (1) (1) (1) (구) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1
CLASSIFICATION: UNCLASS	IFIED
	T ACCOUNT

Can you refer me to someone in VA regarding the Department's guidance on awarding VA disability compensation to Service members undergoing gender reassignment surgeries (i.e., mastectomy, hysterectomy with ovary removal,

removal of both testicles). If the Service member, now Veteran, applies for VA disability will such procedures undertaken as part of gender reassignment also result in an automatic disability rating from the VA?

This may have already been addressed--I'm just looking for the Department's guidance.

(b)(6)

CLASSIFICATION: UNCLASSIFIED CLASSIFICATION: UNCLASSIFIED CLASSIFICATION: UNCLASSIFIED

NOVEMBER 11, 2023

Remarks by President Biden at a Veterans Day Wreath Laying Ceremony | Arlington, VA

Arlington National Cemetery Arlington, Virginia

12:00 P.M. EST

THE PRESIDENT: Thank you. (Applause.) Thank you, thank you, thank you.

My fellow Americans, on this day, 105 years ago, the Great War ended. As news of peace reached the frontlines of France, a young American solider sent a letter home to his parents in Missouri, and I — and I'll quote it. It said, "If only you all could see," he wrote. "Fighting stopped, lanterns shine in every window and door," end of quote.

For those who had fought in this war unlike any war the world had ever seen before, it was a symbol — a reminder that as long as those who stand for freedom, light will always triumph over the darkness.

My fellow Americans, Jill, Vice President Harris, Second Gentleman Emhoff, Secretary McDonough, Secretary Buttigieg is here. Se- – Secretary Mayorkas, Acting Secretary Su, Director Haines, Deputy Secretary Hicks, Vice Chairman Grady, and, most importantly, our veterans and servicemembers and, equally as important, their families.

We come together today to once again honor the generations of Americans who stood on the frontlines of freedom; to once again bear witness to the great deeds of a noble few who risked everything — everything to give us a better future — those who have always, always kept the light of liberty shining bright across the world: our veterans. That's not hyperbole. Our veterans.

Every year on the 11th hour of the 11th day of the 11th month, we gather in this sanctuary of sacrifice to pause, to pay tribute to these patriots of the greatest fighting force in the history of the world.

As Commander-in-Chief, I have no higher honor. As a father of a son who served, I have no greater privilege.

Like it is for so many of you, Veterans Day is personal to Jill and me. On this day, I can still see my son, the Attorney General of Delaware, standing ramrod straight as I pinned his bars on him the day he joined the Army National Guard in Delaware.

I can still feel the overwhelming pride in Major Beau Biden receiving the Bronze Star, the Legion of Merit, and the Delaware Conspicuous Service Cross.

We miss him. I can still hear my wife, Jill, every morning she'd get up to go to school to teach, praying over her cup of coffee during the year he was deployed to Iraq, and six months before that, he was a civilian overseas.

And like it was yesterday, I can also still hear what he told me when he signed up to serve. I said, "Beau, why?" It's the God's truth. He said, "Dad, it's my duty" — "duty."

That was the code my son lived by and the creed that millions of veterans have followed, from Belleau Woods to Baghdad to Gettysburg to Guadalcanal, from Korea to Kandahar and beyond.

Each one linked in a chain of honor that stretches back to our founding days; each one bound by a sacred oath to support and defend. Not a place, not a person, not a president, but an idea — to defend an idea unlike any other in human history. That idea is the United States of America.

We're the only nation in the world — only nation in the world that's built on an idea. Every other nation is based on things like geography, ethnicity, religion. But we're the only nation built on the idea that we are all - all created equal, endowed by our Creator with certain unalienable rights.

We haven't always lived up to it, but because of our veterans, because of you, we've never walked away from it.

For throughout the annals of history, whenever and wherever the force of darkness has sought to extinguish the light of liberty, American veterans have been holding the lantern as high as they can for us all.

They were there when a determined band of patriots sparked a revolution, delivering a nation where everyone – everyone is endowed with certain unalienable rights.

They were there when, less than a century later, they gave our nation a new birth of freedom.

They were there when the forces of fascism brought the fight to the trenches of Europe and the bloody beaches of Normandy.

They were there when called upon to face the oppression in the frozen rice paddies of Korea and the sweltering jungles of Vietnam.

And they were there when darkness came to our shores, signing up for tour after tour after tour to keep our democracy safe and secure these last two decades.

Folks, as a nation, we owe them. We owe you, not just for keeping the flame of freedom burning during the darkest of moments but for serving our communities even after they hang up their uniforms, for inspiring the next generation to serve.

We see this at barracks and bases all across America, where young women and men continue to risk their own safety for the safety of their fellow Americans. And we see it around the world in all the countries I've been in when our troops continue to stand with our allies against the forces of tyranny and terrorism.

To this day, wherever the forces of darkness have sought to extinguish the light of liberty, American troops are there. And right by their side are their As the English poet John Milton wrote, "They also serve who only stand and wait." "They also serve who only stand and wait."

Our veterans are the steel spine of this nation. And their families, like so many of you, are the courageous heart.

Most Americans will never see the sacrifices that you, as family members, also make. They'll never see those holidays, those birthdays made special even with the empty seat at the dinner table.

They'll never see all the packing and unpacking, readying the family to make another move, needing to move to a new school, a new job for the spouse. They'll never see all those nights spent waiting for word from a loved one deployed overseas because you're not sure.

Too often, your sacrifices go without thanks or without acknowledgment.

Well, we must remember only 1 percent -1 percent of our society today protects 99 percent of us. One percent. We owe them. We owe you.

So, to all the families across our nation, to all those who are grieving the loss of a loved one who wore the uniform, to all those with loved ones still missing or unaccounted for, I want to say to you: We see you, we stand with you, and we will not forget.

And just as you have kept the ultimate faith to our country, we will keep the faith with you.

As a nation, I've said many times, we have many obligations, but we have only one truly sacred obligation: to prepare those we send into harm's way and to care for them and their families when they return home. It's not an obligation based on party or politics but on a promise that unites us all.

And together, over the last three years, we've worked to make good on that promise, passing more than 30 bipartisan laws to support our veterans and their families, caregivers, and survivors.

That includes the PACT Act, one of the most significant laws ever to help millions of veterans who were exposed to toxins and burn pits during their military service. Pits the size of football fields that incinerated with the wastes of war: tires, chemicals, jet fuel, and so much more.

Too many of our nation's warriors have served only to return home to suffer from permanent effects of this poisonous smoke. Too many have died.

In the 15 months since I — we wrote and signed the PACT Act, a half a million veterans and their surviving family members have already started receiving benefits. But far, far too many are still are not getting what they need, the care they deserve.

That's why I'm proud to announce that any toxin-exposed veteran who served during any conflict outlined in the PACT Act will be able to roll — be able to enroll in VA healthcare starting March of next year.

We're not stopping there. This past year, we delivered more benefits, processed more claims than ever before in VA history. We expanded resources to end veterans' homelessness, end veterans' poverty, end the silent scourge of suicide, which is taking more veterans than war is.

We're launching a new initiative to protect veterans from scams, because no one should be defrauded by those they defended, for God's sake. (Applause.)

Through Jill's work and others in Joining Forces, we've also announced the most comprehensive set of actions in our nation's history to strengthen economic opportunity for military and veteran spouses, caregivers, and survivors.

And this year, as we marked 75 years of a desegregated military, 75 years of women's integration into the military, and 50 years of an all-volunteer force, we've doubled down on our efforts to ensure all troops, all veterans get the services they need and that no veteran is denied the honor they earned because they were discharged for being L[G]BTQ+. (Applause.)

It matters. It matters to the vet from the state of Delaware who, after years

Case: 24-127114s by Pr Dogument: 7812s Day Rage Lat 35 Ceren File Atline 0/31/2024 hite House of being homeless, after years of living in a tent made of his own uniforms, finally got a roof over his head.

It matters to the vet in Arkansas, who after answering duty's call on 9/11, after dealing with debilitating post-traumatic stress for years, finally is able to receive tailored mental health care that has changed his life. It matters to the vet from Utah. After flying mission after mission over burn pits in Iraq, after being diagnosed with cancer at just 23 years of age, is finally receiving full coverage for his treatment.

It matters. (Applause.)

It matters to the vet from Florida who has been exposed to Agent Orange in Vietnam, after applying and being rejected for benefits four times, finally, as he wrote to me in a letter, quote, "[is] able to get by a little easier now."

Today, we gather not only to honor these stories but the story of all veterans, for it's a story of our nation at its best, a nation that stands as one to forge a better future for all; a nation that faces down fear, generation after generation; a nation that meets darkness with light again and again and again, no matter how high the cost, no matter how heavy the burden.

Ladies and gentlemen, for nearly 250 years, the sacrifices of many of you sitting in front of me and behind me and those who served have kept our country free and our democracy strong.

As that young soldier wrote more than a century ago after World War One ended: "If you only could see. Lanterns shine in every window and door."

Today, we not only see that light of liberty; we live by it. And just like our forebearers, it's on all of us — all of us together — to ask ourselves what can we do, what we must do to keep that light burning, to keep it shining in every window and door for generations to come.

I know we can. I know we will. Because, as our veterans know best, we are the United States of America. And there's n Remarks by Presidentothing, nothing, nothing beyond our capacity. (Applause.) Nothing beyond our capacity when we do it together.

God bless you all. God bless our veterans. And may God protect our — our troops today and always.

Thank you. And thank you for your service. (Applause.)

12:15 P.M. EST

In Reply Refer To: **00REG**



Office of General Counsel Washington DC 20420

February 13, 2024

Subject: Regulatory Impact Analysis for RIN 2900-AR57(F), Reproductive Health Services

I have reviewed the attached Regulatory Impact Analysis and determined the following:

- 1. The Department of Veterans Affairs (VA) has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and has determined that the action is a significant regulatory action under Executive Order 12866.
- 2. This rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601–12.
- 3. This rulemaking is not likely to result in the expenditure of \$100 million or more by State, local, and tribal governments, in the aggregate, or by the private sector, in any one year, under the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.
- 4. Attached please find the relevant Regulatory Impact Analysis document, dated February 13, 2024.

Approved by:

Michael Shores Director Office of Regulation Policy & Management (00REG) Office of General Counsel

(Attachment)

Regulatory Impact Analysis for RIN 2900 - AR57(F)

Title of Rulemaking: Reproductive Health Services

Purpose: To determine the economic impact of this rulemaking.

Statement of Need: In an interim final rule, 87 FR 55287 (September 9, 2022), the Department of Veterans Affairs (VA) determined it needed to amend its medical regulations, in accordance with 38 U.S.C. 501, to ensure that veterans and Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) beneficiaries can obtain abortion counseling and also obtain abortions, irrespective of what laws or policies States and localities may impose, when: (1) the life or health of the pregnant veteran or health of the CHAMPVA beneficiary would be endangered if the pregnancy were carried to term; or (2) the pregnancy is the result of an act of rape or incest.

Summary: VA is finalizing the interim final rule that amended VA's medical regulations to remove the exclusion on abortion counseling in the medical benefits package; established exceptions to the exclusion on abortions for veterans who receive care set forth in that package; and removed the exclusion on abortion counseling and expanded the exceptions to the exclusion on abortions for CHAMPVA beneficiaries.

Analytic Baseline: Most of the quantification that appears in this analysis consists of comparisons relative to an analytic baseline reflecting a hypothetical absence of the preceding interim final rule. The final rule's provisions are the same as the interim final rule's, so there are no incremental benefits, costs or transfers when comparing against a with-IFR analytic baseline.

Benefits: The non-financial benefits to veterans and CHAMPVA beneficiaries will be significant. Pursuant to its mission, VA provides veterans with access to needed medical services and CHAMPVA beneficiaries with access to medically necessary and appropriate medical services. As VA explains in this rulemaking, VA has determined that providing access to abortions is needed when the life or health of the pregnant veteran would be endangered if the pregnancy were carried to term or when the pregnancy is the result of an act of rape or incest. Similarly, VA has determined that providing access to abortions is medically necessary and appropriate to protect the health of CHAMPVA beneficiaries, when the life or health of the pregnant CHAMPVA beneficiary would be endangered if the pregnancy were carried to term or when the pregnancy is the result of an act of rape or incest. Providing these services will also

¹ See, e.g., Abortion Can Be Medically Necessary, AM. COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, Sep. 25, 2019. http://www.acog.org/news/news-releases/2019/09/abortion-can-be-medically-necessary; see also Elizabeth G Raymond & David A Grimes, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States, 119 OBSTETRICS & GYNECOLOGY 215, 216 (2012); Marian F. MacDorman et al., Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues 128 OBSTETRICS & GYNECOLOGY 447 (2016) (finding a 26.6 percent increase in maternal

promote clarity and parity across federal agencies by making VA's policies more consistent with those of other federal providers that currently provide access to certain abortion services.

The rule will not result in a significant benefit to members of the healthcare industry or any other non-VHA entity or individual.

Estimated Impact:

VA anticipates transfers of \$1.8 million in Fiscal Year (FY) 2023 and \$9.5 million from FY 2023 through FY 2027 to provide abortion and abortion counseling services to veterans and CHAMPVA beneficiaries, including beneficiary travel. VA has provided these estimates in Table 1 below and further information regarding these obligations is discussed in the Assumptions and Methodology section of this analysis.

Table 1: Total Budgetary Impact (Services)

		Treatment s (Thousands)	Beneficiary Travel (Thousands)	Total Expenditures (Thousands)			
Fiscal Year	Cases	Cases Transfers		Cases	Total Transfers		
2023	1,024	\$606	\$1,151	1,024	\$1,757		
2024	1,033	\$630	\$1,196	1,033	\$1,826		
2025	1,043	\$655	\$1,243	1,043	\$1,898		
2026	1,053	\$682	\$1,291	1,053	\$1,973		
2027	1,061	\$708	\$1,342	1,061	\$2,050		
5-Year Total	5,213	\$3,281	\$6,223	5,213	\$9,504		
2028	1,067	\$733	\$1,394	1,067	\$2,127		
2029	1,072	\$758	\$1,448	1,072	\$2,206		
2030	1,074	\$782	\$1,505	1,074	\$2,287		
2031	1,076	\$807	\$1,564	1,076	\$2,371		
2032	1,075	\$830	\$1,625	1,075	\$2,455		
10-Year Total	10,578	\$7,190	\$13,759	10,578	\$20,949		

Assumptions and Methodology:

Cost of Abortion Methodology

Utilization Projection

mortality rates between 2000 and 2014); and Victoria L.Meah, et al., Cardiac output and related haemodynamics during pregnancy: a series of meta-analyses, HEART J., 102:518-526 (2016).

The number of abortions provided in the first year of implementation of the interim final rule was significantly lower than the original estimate. VA anticipates that the number of abortions in subsequent years will increase as more Veterans and CHAMPVA beneficiaries access available health care. Notwithstanding the discrepancy between VA's estimates and the number of actual abortions provided in the first year of implementation, VA believes the assumptions used to create the estimates were reasonable under the circumstances. While data on the frequency and cost of abortions in the United States under the circumstances allowed by the interim final rule is limited, VA notes that the original estimates were based on the best available data on the frequency and cost of abortions needed to preserve the life or health of the pregnant person, or when pregnancy is the result of rape or incest in active duty military and Veteran populations that most closely reflects the population of pregnant people served by VA, as explained below.

Included in the cost projections is the total number of female veterans under age 50 enrolled in VA by year based on the 2021 Base Year 2020 (BY20) Enrollee Health Care Projection Model (EHCPM).

The number of CHAMPVA beneficiaries includes certain spouses, children, survivors, and caregivers of veterans who meet specific eligibility criteria under 38 U.S.C. 1781(a). Spouses were limited to females. VA made the following simplifying assumptions: spouses are the same age as the sponsor, children are all age 15 to 25 and 50 percent female, parents are all over age 50 and therefore assumed to have no pregnancy related costs, and siblings and other caregivers are the same age as the sponsor and 50 percent female.

The portion of veterans who would seek an abortion when the life of the pregnant veteran is endangered if the pregnancy is carried to term and the portion of veteran enrollees and CHAMPVA beneficiaries who would seek an abortion when the pregnancy is the result of rape or incest is based on data from the Department of Defense (DoD), which provides abortions in similar circumstances. Based on data from 2013 to 2016, which is the most current, comprehensive data available, 0.005 percent of active-duty servicemembers of reproductive age had abortions for these reasons. VA assumed the same frequency of these abortions for veteran enrollees and CHAMPVA beneficiaries.

The portion of veterans and CHAMPVA beneficiaries who would seek an abortion when the health of the pregnant veteran or CHAMPVA beneficiary is endangered if the pregnancy is carried to term is based on data reflecting rates of high-risk pregnancies and studies of severe maternal morbidity rates in the general population. VA recognizes that veterans and CHAMPVA beneficiaries may experience different rates of high-risk pregnancies and severe maternal morbidity than the general population. However, data from the general population was the best available data for the purpose of this analysis, and VA lacks a basis for quantifying any differences in such rates between the population covered by this rule and the general population. Accordingly, VA reasonably relied on the general population data for the purposes of this analysis.

VA assumed that all abortions for veterans and CHAMPVA beneficiaries covered under this proposal will be paid for or provided by VA. To the extent that some or all of this care will be paid for by other types of health care coverage, the effect would be a reduced cost for VA.

Cost Projection

The cost of abortion procedures is based on a review of self-pay abortion charges in the US which shows abortions occurring early in a pregnancy cost approximately \$500 and abortions occurring later in a pregnancy cost approximately \$1,700.² Self-pay charges may not be representative of contracted VHA reimbursement levels.

The cost of an abortion for those who would seek an abortion due to the life or health of the pregnant patient being at risk or pregnancy as a result of rape or incest is assumed to be \$500 in FY 2020. The analysis assumes a large majority of these abortions will occur early in the pregnancy.³ While some abortions may occur later in pregnancy with a higher cost, these are expected to occur at very low frequency, consistent with national data.³

These costs are increased to reflect medical inflation over time.

This expenditure estimate reflects the costs associated with abortion treatment. It does not account for cost avoidance associated with the health sequelae resulting from a failure to perform a medically necessary abortion on the pregnant veteran or CHAMPVA beneficiary. This information is extremely difficult to estimate and thus not quantified. The rule is fully justified based on the VA's mission without considering this cost avoidance.

Cost of Beneficiary Travel Methodology

As noted above, the number of abortions provided in the first year of implementation of the interim final rule was significantly lower than the original estimate reflected in the interim final rule. However, based on the assumptions and data described herein, VA estimates that VA will provide or cover 1000 abortions annually.

Of these, one-half (500) are assumed to be medication abortion and thus would not require travel. VA further assumed that the remaining half (500) will be abortion procedures. These assumptions are based on national statistics related to abortion provision, which show that about 50% of abortions provided in the United States are

² https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01528

³ Kortsmit K, Nguyen AT, Mandel MG, Hollier LM, Ramer S, Rodenhizer J, Whiteman MK. Abortion Surveillance - United States, 2021. MMWR Surveill Summ. 2023 Nov 24;72(9):1-29. doi: 10.15585/mmwr.ss7209a1. PMID: 37992038; PMCID: PMC10684357

medication abortion, with the other approximately 50% being abortion procedures.⁴ VA acknowledges that this rule covers a narrower subset of abortions than national data covering all abortions provided in the general population; however, VA is not aware of similar data covering only those abortions occurring in circumstances covered by this rule. Further, VA lacks a basis for quantifying any differences in the rates of medication abortion versus abortion procedures between the circumstances covered by this rule and all abortions provided nationwide. Accordingly, VA reasonably relied on the national statistics for the purposes of this analysis.

VA further assumed that 50 percent of abortion procedures (approximately 250) for veterans may require travel. Depending on the resources available at the local VA facility to provide abortion procedures, abortion procedures may require care in the community or care at another VA facility. When abortion is provided in the community, access to abortion is affected by state laws governing access to abortion. Approximately 50 percent of Veterans of childbearing potential live in states with highly restrictive abortion laws that may make access to abortion procedures in the community essentially unavailable in those states.

Of the 250 veterans who may require travel for abortion services annually, VA estimates that 72 percent will be eligible for beneficiary travel. Eligibility for beneficiary travel is governed by 38 U.S.C. 111 and 38 CFR part 70. Among other criteria, veterans with a service-connected disability rated at 30 percent or more are eligible for reimbursement for travel in connection with VA authorized appointments. Seventy-two percent of current veteran users of VHA who are capable of pregnancy have a service-connected disability rated at 30 percent or more and are thus eligible for beneficiary travel. Therefore, 180 veterans are estimated to use beneficiary travel for an abortion. VA allows veterans traveling for medical care to travel with an attendant if needed to support them in their care. For the purposes of this cost estimate, VA assumed all veterans who travel for abortions may need an attendant.

VA assumed that 1 percent of abortions (10) may require a special mode of travel to include interfacility travel (e.g., an air ambulance). This assumption is based on what is known about the frequency of when emergency abortion might be required for a critically ill and hospitalized patient.⁵

Cost Projection

The average cost of beneficiary travel for veterans who would seek abortion procedures is assumed to be \$1,599.25 per veteran in 2023. The average cost to travel for

⁴ Kortsmit K, Nguyen AT, Mandel MG, Hollier LM, Ramer S, Rodenhizer J, Whiteman MK. Abortion Surveillance - United States, 2021. MMWR Surveill Summ. 2023 Nov 24;72(9):1-29. doi: 10.15585/mmwr.ss7209a1. PMID: 37992038; PMCID: PMC10684357

⁵ MacDonald A, Gershengorn HB, Ashana DC. The Challenge of Emergency Abortion Care Following the Dobbs Ruling. JAMA. 2022 Nov 1;328(17):1691-1692.

veterans' attendants is assumed to be \$2,019.00 per attendant in 2023. The average cost for special mode travel is assumed to be \$50,000 per veteran in 2023.

Paperwork Reduction Act: This rulemaking contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–21.

Alternative Policy Approaches: VA is finalizing an interim final rule that has been in effect since September 9, 2022. In *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), the Supreme Court overruled *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992). Numerous States responded by enforcing restrictions on abortion that have made, and will likely continue to make, it very difficult for many veterans and CHAMPVA beneficiaries to receive comprehensive reproductive health care in their communities, creating urgent risks to the lives and health of pregnant veterans and CHAMPVA beneficiaries. It was critical that this rule be published and effective immediately to ensure pregnant veterans and CHAMPVA beneficiaries have access to this important care. Since the IFR's issuance, it remains the case that the health care services permitted under the IFR are "needed" within the meaning of VA's general treatment authority with respect to veterans, 38 U.S.C. 1710, and that providing access to such care is medically necessary and appropriate to protect the health of CHAMPVA beneficiaries, 38 U.S.C. 1781; 38 CFR 17.270(b).

Submitted by:

Shereef Elnahal, M.D., M.B.A. Under Secretary for Health, Department of Veterans Affairs

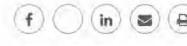
Date: February 13, 2024



The independent source for health policy research, polling, and news.

2023 Employer Health Benefits Survey

Published: Oct 18, 2023



REPORT

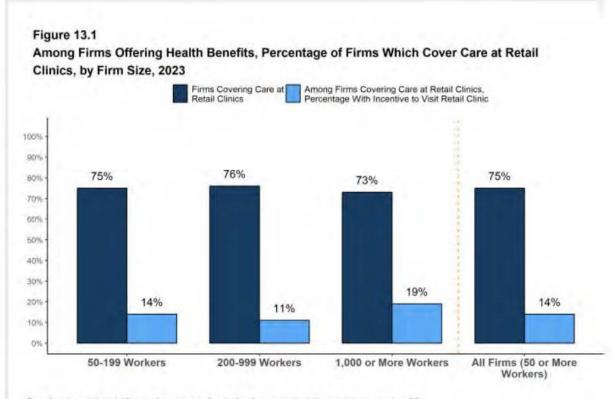
Section 13: Employer Practices, Telehealth, Provider Networks, **Coverage Limits and Coverage for Abortion**

Employers frequently review and modify their health plans to incorporate new options or adapt to new circumstances.

HEALTH CLINICS

- Many employers cover health services provided through retail health clinics. These clinics can be found in supermarkets, pharmacies or other retail locations and provide preventive services, such as vaccines and flu shots. Some also treat minor illnesses.
 - Among firms with 50 or more employees that offer health benefits, 75% say their largest health plan covers services provided through these clinics [Figure 13.1]. This percentage is similar across firm sizes.
 - Among firms with 50 or more employees whose largest plan covers health services received in retail clinics, 14% provide a financial incentive, such as lower cost sharing, for workers to use a retail health clinic instead of visiting a traditional physician's office [Figure 13.1].
- Some employers provide health services to their employees through clinics that they establish or sponsor at or near their place of work. On-site and near-site clinics may treat work-related injuries, and may also provide other health services.
 - Among firms with 50 or more employees that offer health benefits, 16% have an onsite or a near-site health clinic for their employees at one or more of their workplace locations. Firms with 1,000 to 4,999 workers and firms with 5,000 or more workers are more likely than smaller firms to have one of these clinics [Figure 13.3].

 Among firms reporting that they have an on-site or near-site clinic at one of their workplace locations, 34% say they have an on-site clinic, 57% say that they have a near-site clinic, and 10% say that they have both types of clinics. Generally, smaller firms are more likely to say that they have near-site clinics and larger firms are more likely to say that they have on-site clinics.

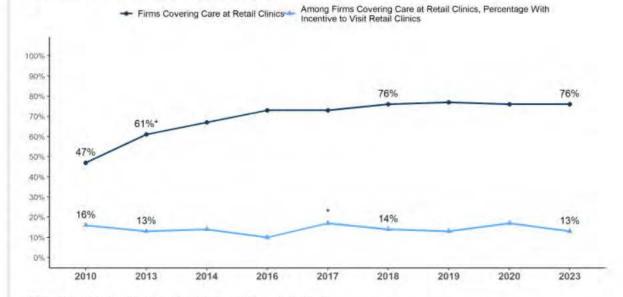


Tests found no statistical difference from estimate for all other firms not in the indicated size category (p < .05). NOTE: A retail clinic is a health care clinic located in a retail store, supermarket, or pharmacy that treats minor illnesses and provides preventive health care services such as flu shots. Financial incentives include lower cost sharing for care received at refail clinics instead of traditional physician offices. Firms with multiple plans were asked about their plan with the largest enrollment. SOURCE: KFF Employer Health Benefits Survey, 2023

(https://www.kff.org/?attachment_id=601828)

Figure 13.1: Among Firms Offering Health Benefits, Percentage of Firms Which Cover Care at Retail Clinics, by Firm Size, 2023

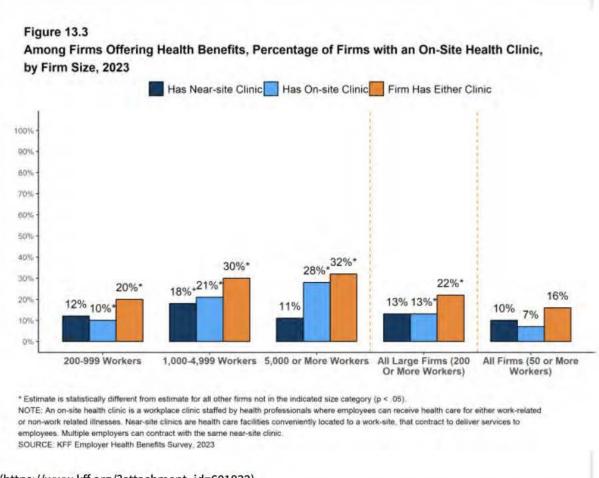
Figure 13.2 Among Large Firms Offering Health Benefits, Percentage of Firms Which Cover Care at Retail Clinics and That Have a Financial Incentive for Workers to Visit Retail Clinics Instead of a Physician's Office, 2010-2023



^{*} Estimate is statistically different from estimate for the previous year shown (p < .05). NOTE: A retail clinic is a health care clinic located in a retail store, supermarket, or pharmacy that treats minor illnesses and provides preventive health care services such as flu shots. Financial incentives include lower cost sharing for care received at retail clinics instead of traditional physician offices. Large Firms have 200 or more workers. Firms with multiple plans were asked about their plan with the largest enrollment. SOURCE: KFF Employer Health Benefits, Survey, 2018-2023; Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2010-2017

(https://www.kff.org/?attachment_id=601830)

Figure 13.2: Among Large Firms Offering Health Benefits, Percentage of Firms Which Cover Care at Retail Clinics and That Have a Financial Incentive for Workers to Visit Retail Clinics Instead of a Physician's Office, 2010-2023



(https://www.kff.org/?attachment_id=601832)

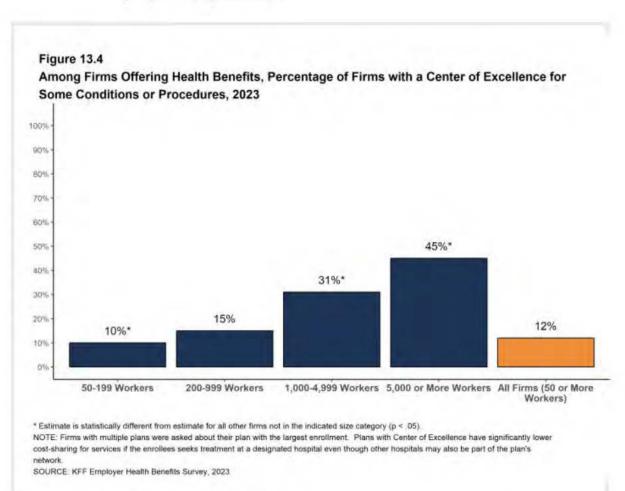
Figure 13.3: Among Firms Offering Health Benefits, Percentage of Firms With an On-Site Health Clinic, by Firm Size, 2023

CENTERS OF EXCELLENCE

"Centers of Excellence" are facilities or providers which health plans and employers single out as providers of exceptionally high-value specialty care for specific conditions. Plans and employers may encourage or require enrollees to use these designated providers to receive coverage for certain types of care. Centers of excellence may provide care that is particularly complex or specialized, such as organ transplants, or care that employers and health plans believe may be subject to abuse or poor care delivery, such as care for musculoskeletal injuries.

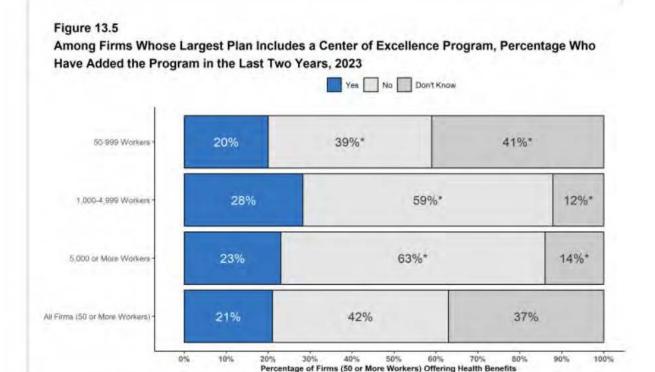
- Among firms with 50 or more employees that offer health benefits, 12% said that they offered a center of excellence program in 2023 [Figure 13.4].
 - Larger firms are much more likely to say that they have a center of excellence program than smaller employers, with 31% of firms with 1,000 to 4,999 workers and 45% of firms with 5,000 or more workers saying that they offer this kind of program Figure 13.4].

- Among firms with a center of excellence program, 21% have introduced a new center of excellence program within the last two years [Figure 13.5].
- Employers with 200 or more employees with a center of excellence program were asked about the types of services included in these programs.
 - Among these employers, 42% have a center of excellence program for back or spine surgery, 28% for substance use disorders, 30% for mental health conditions, 31% for bariatric surgery, and 45% for joint replacement [Figure 13.6].
 - Firms with 5,000 or more employees are less likely than other large firms with center of excellence programs to have a program for substance use or mental health conditions and more likely to have a program for bariatric surgery.
 - It should be noted that a significant share of large employer respondents answered "don't know" to the questions about the types of services covered by their center of excellence programs [Figure 13.6].



(https://www.kff.org/?attachment_id=601834)

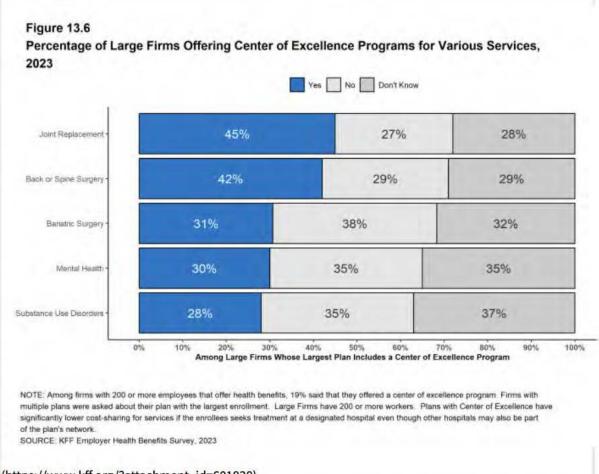
Figure 13.4: Among Firms Offering Health Benefits, Percentage of Firms With a Center of Excellence for Some Conditions or Procedures, 2023



* Estimates are statistically different from estimate for all other firms not in the indicated category within each firm size (p < .05). NOTE: Firms with multiple plans were asked about their plan with the largest enrollment. Among firms with 50 or more employees that offer health benefits, 12% offered a center of excellence program. Plans with Center of Excellence have significantly lower cost-sharing for services if the enrollees seeks treatment at a designated hospital even though other hospitals may also be part of the plan's network. SOURCE: KFF Employer Health Benefits Survey, 2023

(https://www.kff.org/?attachment_id=601836)

Figure 13.5: Among Firms Whose Largest Plan Includes a Center of Excellence Program, Percentage Who Have Added the Program in the Last Two Years, 2023



(https://www.kff.org/?attachment_id=601838)

Figure 13.6: Percentage of Large Firms Offering Center of Excellence Programs for Various Services, 2023

TELEMEDICINE

Coverage for telemedicine benefits, which had been growing steadily before the COVID-19 pandemic, skyrocketed during the initial lockdown period. Both state and federal policymakers took steps to reduce regulatory barriers to telemedicine services, while employers and insurers also took steps to make it easier for patients to use them. We asked employers about their telemedicine benefit offerings, as well as whether they view these benefits as an important source of access to health care in the future.

We define telemedicine as the delivery of health care services through telecommunications from a provider to a patient who is at a remote location, including video chat and remote monitoring. This generally does not include the mere exchange of information via email, exclusively web-based resources, or online information that a plan may make available, unless a health professional provides information specific to the enrollee's condition.

Among firms with 50 or more workers offering health benefits, 91% cover the provision of some health care services through telemedicine in their largest health plan, similar to the

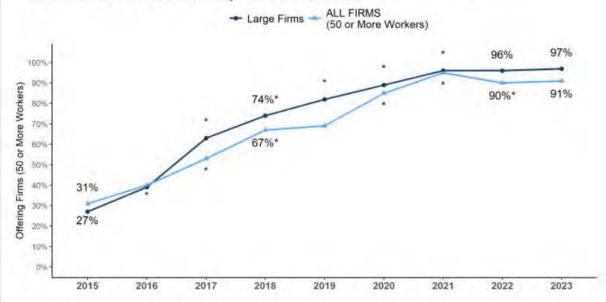
previous year (90%) [Figure 13.7]. Large firms are more likely than small firms (50-199 workers) to cover telemedicine services (97% vs. 89%) [Figure 13.7].

- Among firms with 50 or more employees offering telemedicine services, 20% use a specialized telemedicine service provider, such as Teledoc, Doctor on Demand, or MDLIVE, 59% offer these services through their health plan, 19% through both a specialized telemedicine provider and their health plan, and 2% through some other arrangement [Figure 13.8].
 - Small firms are more likely than larger firms to provide telemedicine services only through their health plan (63% vs. 47%) [Figure 13.8].
 - Large firms are more likely than small firms to provide telemedicine services through a specialized telemedicine provider (26% vs. 17%) or through both their health plan and a specialized telemedicine provider (24% vs. 17%) [Figure 13.8].
- Among firms with 50 or more employees offering health benefits, 2% of smaller firms (50-199 workers) and 5% of larger firms (200 or more workers) had contracted with a new telemedicine service provider within the last 12 months [Figure 13.9].

With the effects of the pandemic waning, medical services are generally available on an inperson basis and many employees have partially or fully returned to their workplaces. With this context, we asked employers how important they felt telemedicine would be in providing care to employees going forward, both overall and for several specific types of services. Among firms with 50 or more enrollees offering health benefits:

- Overall Twenty-eight percent say that telemedicine will be "very important" in providing access to enrollees in the future, and another 32% say that it will be "important" to providing access to these services [Figure 13.12].
- **Behavioral Health Services** Forty-one percent say that telemedicine will be "very important" in providing access to behavioral health services in the future, and another 30% say that it will be "important." Larger firms (1,000 or more workers) are more likely than smaller firms to say that telemedicine will be "very important" to providing access to these services. (57% vs. 40%).
 - **Primary Care** Twenty-seven percent say that telemedicine will be "very important" in providing access to primary care in the future, and another 34% say that it will be "important."
 - **Specialty Care** Sixteen percent say that telemedicine will be "very important" in providing access to specialty care in the future, and another 30% say that it will be "important."
 - **Enrollees in Remote Areas** Forty-three percent say that telemedicine will be "very important" in providing future access to care for enrollees in remote areas, and another 26% say that it will be "important."

Figure 13.7 Among Firms Offering Health Benefits, Percentage of Firms Whose Plan with the Largest Enrollment Covers Telemedicine, by Firm Size, 2015-2023



^{*} Estimate is statistically different from estimate for the previous year shown (p < 05).

NOTE: Telemedicine is health care services provided to a patient from a provider who is at a different location, including video chat and remote monitoring. We do not include email, exclusively web-based non-interactive resources, or online information a plan may make available unless a health professional provides information specific to the enrollee's condition. Large Firms have 200 or more workers. Firms with multiple plans were asked about their plan with the largest enrollment.

SOURCE KFF Employer Health Benefits Survey, 2018-2023; Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2015-2017

(https://www.kff.org/?attachment_id=601840)

Figure 13.7: Among Firms Offering Health Benefits, Percentage of Firms Whose Plan With the Largest Enrollment Covers Telemedicine, by Firm Size, 2015-2023

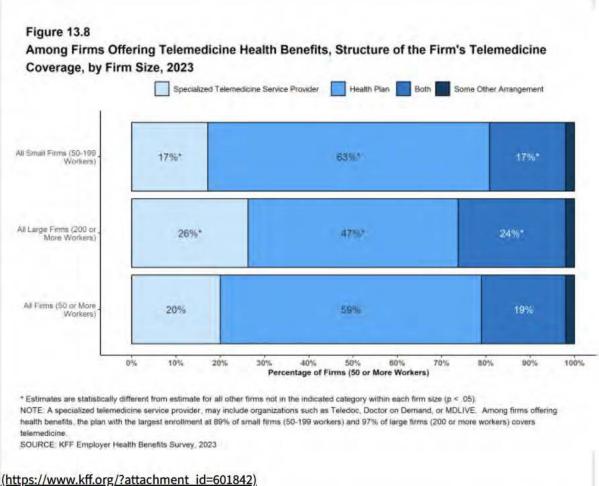
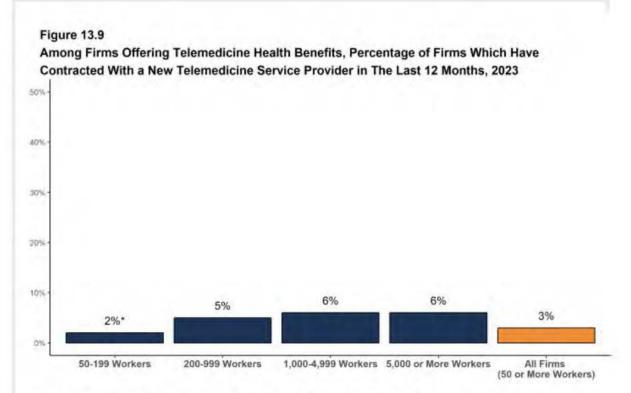


Figure 13.8: Among Firms Offering Telemedicine Health Benefits, Structure of the Firm's Telemedicine Coverage, by Firm Size, 2023

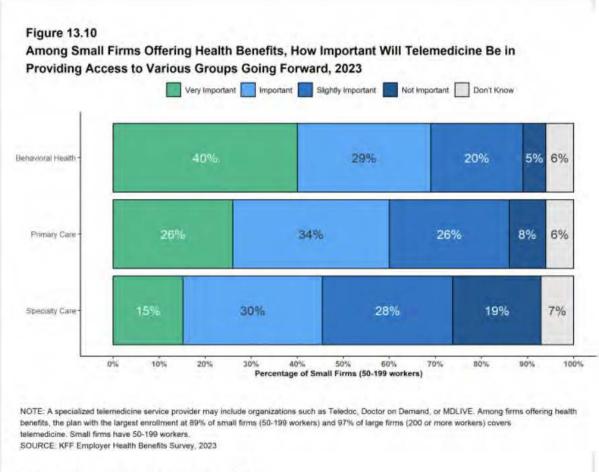


* Estimate is statistically different from estimate for all other firms not in the indicated size category (p < .05). NOTE: A specialized telemedicine service provider may include organizations such as Teledoc, Doctor on Demand, or MDLIVE. Among firms offering health benefits, the plan with the largest enrollment at 89% of small firms (50-199 workers) and 97% of large firms (200 or more workers) covers telemedicine

SOURCE: KFF Employer Health Benefits Survey, 2023

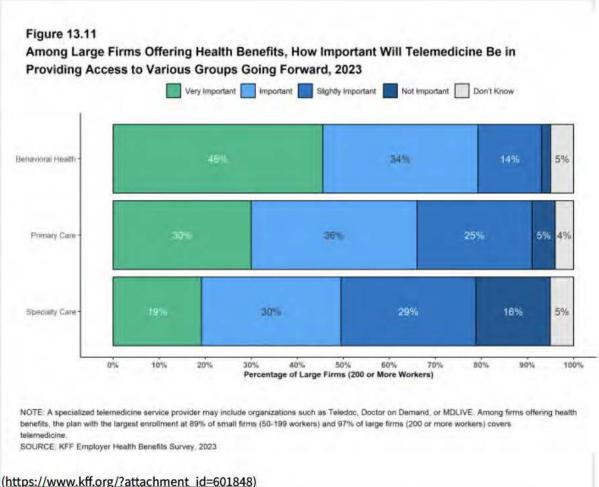
(https://www.kff.org/?attachment_id=601844)

Figure 13.9: Among Firms Offering Telemedicine Health Benefits, Percentage of Firms Which Have Contracted With a New Telemedicine Service Provider in the Last 12 Months, 2023



(https://www.kff.org/?attachment_id=601846)

Figure 13.10: Among Small Firms Offering Health Benefits, How Important Will Telemedicine Be in Providing Access to Various Groups Going Forward, 2023



(https://www.kff.org/?attachment_id=601848)

Figure 13.11: Among Large Firms Offering Health Benefits, How Important Will Telemedicine Be in Providing Access to Various Groups Going Forward, 2023

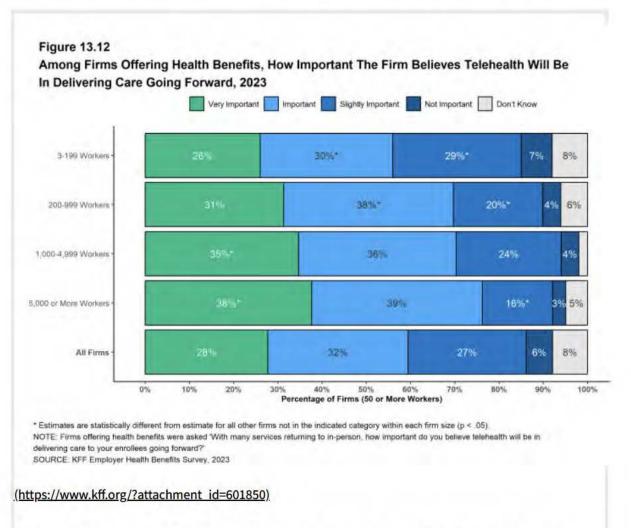


Figure 13.12: Among Firms Offering Health Benefits, How Important the Firm Believes Telehealth Will Be in Delivering Care Going Forward, 2023

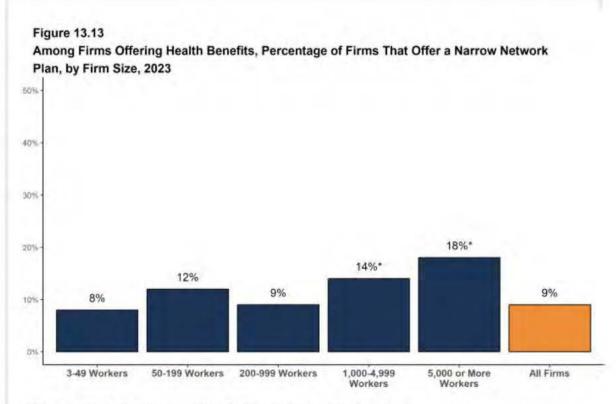
PROVIDER NETWORKS

Firms and health plans structure their networks of providers to ensure access to care, and to encourage enrollees to use providers who are lower cost, or who provide better care.

- Some employers offer a health plan with a relatively small, or narrow, network of providers to their employees. Narrow network plans limit the number of providers that can participate in order to reduce costs, and are generally more restrictive than standard HMO networks.
 - Nine percent of firms offering health benefits report that they offer at least one plan that they considered to be a narrow network plan, the same as the percentage reported last year (9%) [Figure 13.13].
 - Firms with 1,000 to 4,999 workers and firms with 5,000 or more workers offering health benefits are more likely than firms of other sizes to offer at least one plan with a narrow network [Figure 13.13].
- Firms offering health benefits were asked whether they believed that the provider network for their health plan with the largest enrollment provided timely access to certain

services.

- Over nine in ten (91%) firms offering health benefits believe that there are a sufficient number primary care providers in the plan's networks to provide timely access to services for workers and their family members [Figure 13.15].
- By contrast, only 67% of firms offering health benefits believe that there is a sufficient number of mental health providers in the plan's network to provide timely access to services for workers and their family members [Figure 13.15]. Large firms are less likely than small firms to say that there were a sufficient number of these providers to provide timely access to behavioral health services [Figure 13.16].
- Similar to the percentage for mental health providers, 59% of firms offering health benefits believe that there is a sufficient number of substance use providers in the plan network to provide timely access to substance use services for workers and their family members [Figure 13.15]. Thirty-one percent of small firms and 23% of large firms offering health benefits did not know the answer to this question [Figure 13.16].
- Among larger firms offering health benefits, 30% of firms with 1,000 to 4,999 workers and 44% of firms with 5,000 or more workers took steps within the past 12 months to increase the number of mental health providers in their plan networks [Figure 13.17]
- Firms offering health benefits are generally satisfied with the accuracy of plan provider directories, with 31% reporting they are "very satisfied" and an additional 58% saying they are "satisfied" with their accuracy [Figure 13.18].



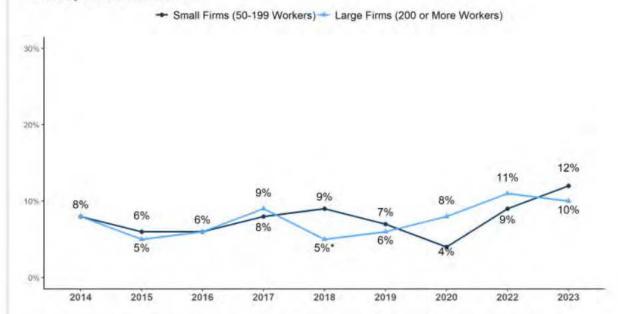
^{*} Estimate is statistically different from estimate for all other firms not in the indicated size category (p < .05). NOTE: Narrow network plans limit the number of providers that can participate in order to reduce costs and generally are more restrictive than standard HMO networks.

SOURCE: KFF Employer Health Benefits Survey, 2023

(https://www.kff.org/?attachment_id=601852)

Figure 13.13: Among Firms Offering Health Benefits, Percentage of Firms That Offer a Narrow Network Plan, by Firm Size, 2023

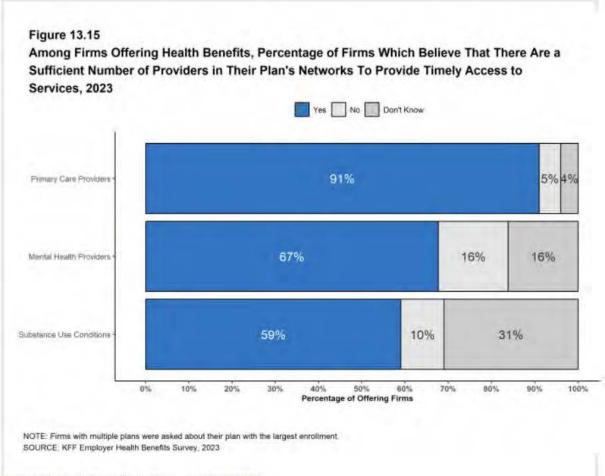
Figure 13.14 Among Firms Offering Health Benefits, Percentage of Firms That Offer a Narrow Network Plan, by Firm Size, 2014-2023



^{*} Estimate is statistically different from estimate for the previous year shown (p < .05). NOTE: This question was asked of offering firms with 50 or more workers in 2014, but has since been asked of all offering firms regardless of firm size. In 2023, 9% of all offering firms offer a plan that could be considered a narrow network plan Narrow network plans limit the number of providers that can participate in order to reduce costs and generally are more restrictive than standard HMO networks. SOURCE KFF Employer Health Benefits Survey, 2018-2023; Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2014-2017

(https://www.kff.org/?attachment_id=601854)

Figure 13.14: Among Firms Offering Health Benefits, Percentage of Firms That Offer a Narrow Network Plan, by Firm Size, 2014-2023



(https://www.kff.org/?attachment_id=601856)

Figure 13.15: Among Firms Offering Health Benefits, Percentage of Firms Which Believe That There Are a Sufficient Number of Providers in Their Plan's Networks to Provide Timely Access to Services, 2023

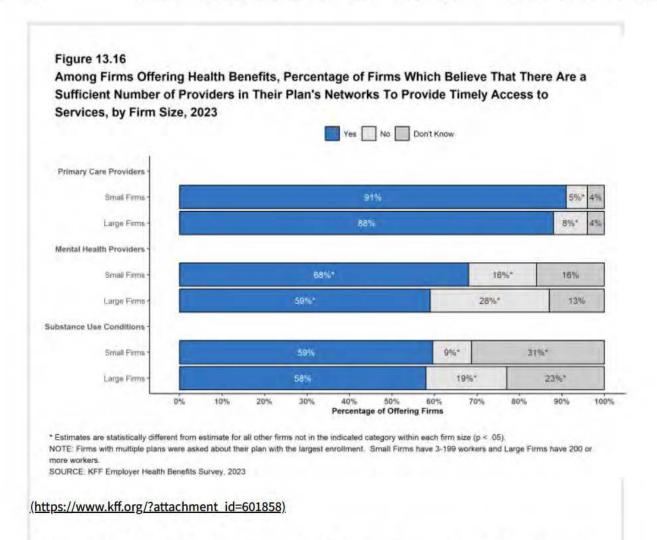
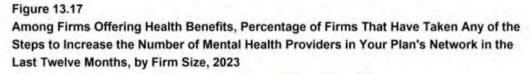
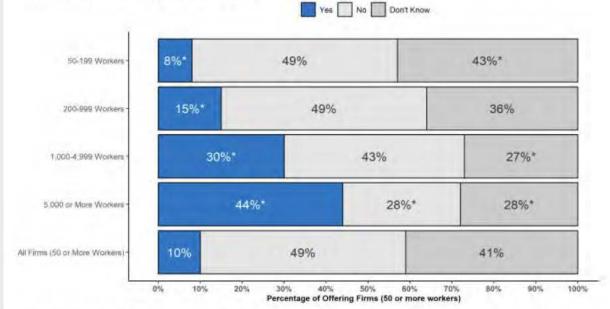


Figure 13.16: Among Firms Offering Health Benefits, Percentage of Firms Which Believe That There Are a Sufficient Number of Providers in Their Plan's Networks to Provide Timely Access to Services, by Firm Size, 2023





^{*} Estimate is statistically different from estimate for all other firms not in the indicated size category (p < .05). NOTE: Firms with multiple plans were asked about their plan with the largest enrollment. SOURCE: KFF Employer Health Benefits Survey, 2023

(https://www.kff.org/?attachment_id=601860)

Figure 13.17: Among Firms Offering Health Benefits, Percentage of Firms That Have Taken Any of the Steps to Increase the Number of Mental Health Providers in Your Plan's Network in the Last Twelve Months, by Firm Size, 2023

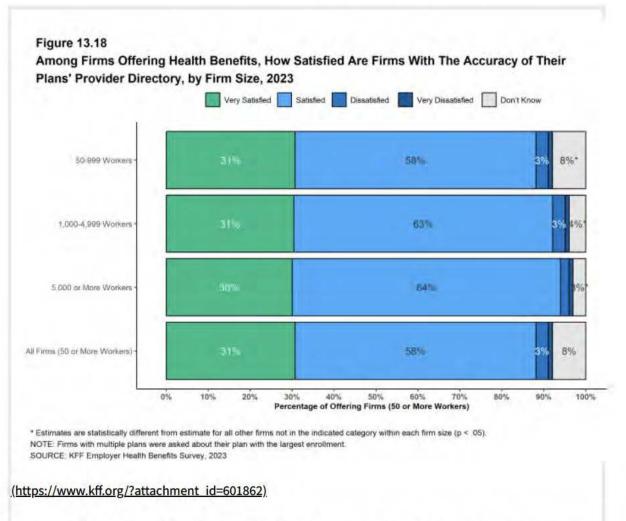


Figure 13.18: Among Firms Offering Health Benefits, How Satisfied Are Firms With the Accuracy of Their Plans' Provider Directory, by Firm Size, 2023

PLAN MANAGEMENT AND COVERAGE LIMITS

Employers use health benefits to attract and keep workers, making them an important part of the overall compensation that employers provide. Employers therefore have strong interest in assuring that their health benefit plans perform well and are viewed favorably by their workers. At the same time, health benefits are expensive. Therefore, employers manage plan costs within the broader context of the overall compensation they offer to their employees.

- Employers with 50 or more employees offering health benefits were asked about their views regarding the level of concern their employees had over certain aspects of their health benefit plans:
 - Appointments Twenty percent of these employers believe that their employees have a 'high' level of concern about their ability to schedule timely appointments for care, and another 29% believe that their employees have a 'moderate' level of concern [Figure 13.20].

- **Prior Authorization** Twelve percent of these employers believe that their employees have a 'high' level of concern about the complexity of prior authorization requirements in their health plan, and another 35% believe that their employees have a 'moderate' level of concern [Figure 13.20].
- Finding In-Network Providers Nine percent of these employers believe that their employees have a 'high' level of concern about the difficulty of finding in-network providers, and another 17% believe that their employees have a 'moderate' level of concern [Figure 13.20].
- **Affordability of Cost Sharing** Twenty-five percent of these employers believe that their employees have a 'high' level of concern about the affordability of cost sharing, and another 33% believe that their employees have a 'moderate' level of concern [Figure 13.20].
- Employers offering health benefits were asked whether they anticipated making certain changes to their health benefits over the next two years:
 - High-Cost Providers Nine percent of these employers plan to remove high-cost providers from their networks [Figure 13.22].
 - **Increase Cost-Sharing** Seventeen percent of these employers plan to increase cost sharing, such as copayments and deductibles. Large firms are more likely than smaller firms to anticipate making this change (26% vs. 17%) [Figure 13.21].
 - Increase Worker's Premium Contributions Twenty-three percent of these employers plan to increase worker's premium contributions. Large firms are more likely than smaller firms to anticipate making this change (46% vs. 22%) [Figure 13.21].
 - **Reduce Covered Services** Four percent of these employers plan to reduce the number of covered services [Figure 13.22].
 - Move to an HSA-Qualified Plan Twelve percent of these employers plan to offer an HSA-qualified health plan [Figure 13.22].
 - Increase Utilization Management Six percent of these employers plan to increase utilization management, such as prior authorization of services. Large firms are more likely than smaller firms to anticipate making this change (11% vs. 5%) [Figure 13.21].
- One way that employers manage health plan costs is by limiting the number of services that enrollees can receive for certain types of care. The Affordable Care Act (ACA) generally prohibits health plans from imposing annual or lifetime dollar limits on benefits but does not prohibit plans from limiting the number of visits or services provided. The Mental Health Parity and Addiction Equity Act (MHPAEA) prohibits treatment limits that are more restrictive on mental health and substance use disorder benefits than on medical/surgical benefits. Large employers (200 or more workers) offering health benefits were asked if their largest health plan had limits on the number of visits they covered for certain types of care. Among these employers:
 - Fifty-one percent have limits on the number of covered visits for physical rehabilitation or physical therapy. Employers with 1,000 or more employees are

more likely than firms with 200 to 999 employees to have this type of limit (59% vs. 49%) [Figure 13.23].

- Twenty-one percent have limits on the number of covered visits for mental health services. Employers with 5,000 or more employees are less likely than smaller firms to have this type of limit [Figure 13.23].
- Fifty-four percent have limits on the number of covered visits for chiropractic care. Employers with 1,000 or more employees are more likely than firms with 200 to 999 employees to have this type of limit (64% vs. 51%) [Figure 13.23]
- Prior authorization is a tool used by health plans to review the appropriateness of certain services or prescriptions before they are covered. It may be used as an additional layer of scrutiny for services that plans believe are often recommended inappropriately, or to encourage less expensive alternatives. Prior authorization practices have recently come under public scrutiny over concerns of delayed care and complexity for plan enrollees.
 - Employers with 50 or more employees offering health benefits were asked if they had increased the number of services subject to prior authorization in their health plan with the largest enrollment in the last two years. Among these employers, 12% said they had increased the services subject to prior authorization over the period. A large share of both small and large employer respondents did not know the answer to this question [Figure 13.24].

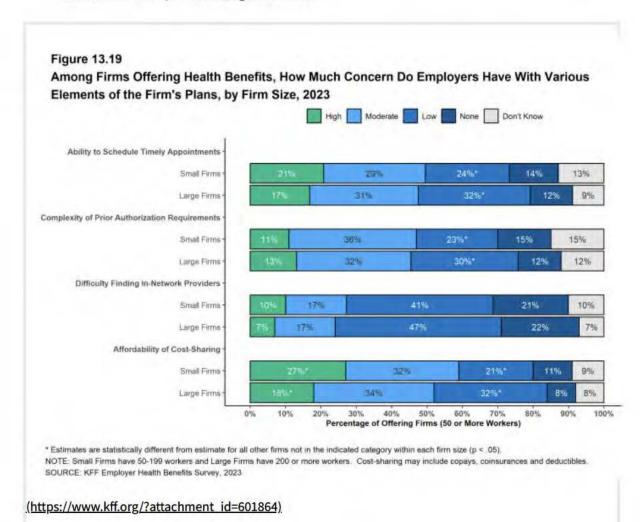


Figure 13.19: Among Firms Offering Health Benefits, How Much Concern Do Employers Have With Various Elements of the Firm's Plans, by Firm Size, 2023

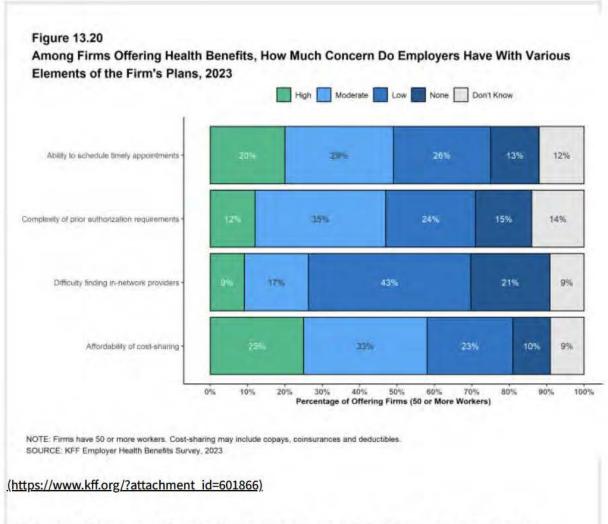
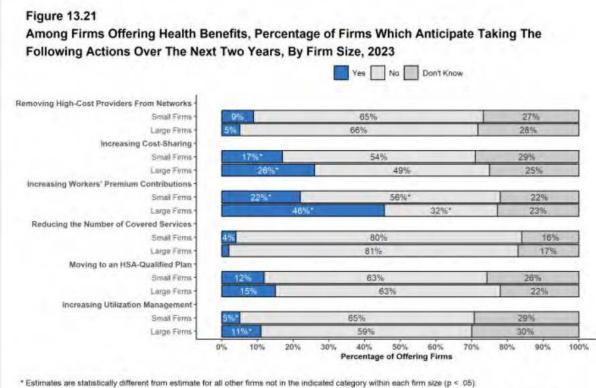


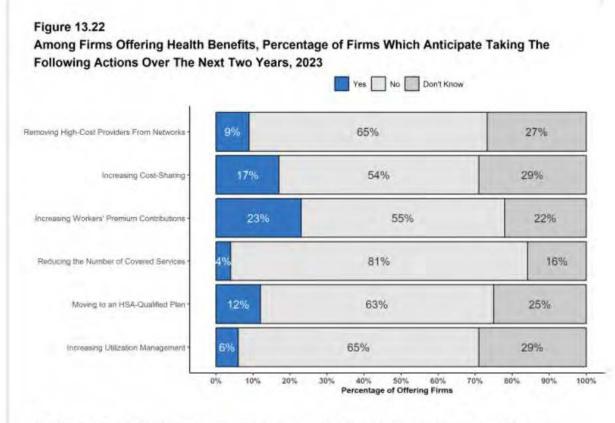
Figure 13.20: Among Firms Offering Health Benefits, How Much Concern Do Employers Have With Various Elements of the Firm's Plans, 2023



NOTE: Small Firms have 3-199 workers and Large Firms have 200 or more workers. Cost-sharing may include copays, coinsurances and deductibles. Increased utilization management may include additional prior authorization requirements. Firms with 100% of their enrollment in an HSA-qualified plan are not included in the average of those moving to an HSA-qualified plan. SOURCE: KFF Employer Health Benefits Survey, 2023

(https://www.kff.org/?attachment_id=601868)

Figure 13.21: Among Firms Offering Health Benefits, Percentage of Firms Which Anticipate Taking the Following Actions Over the Next Two Years, by Firm Size, 2023



NOTE: Cost-sharing may include copays, coinsurances and deductibles. Increased utilization management may include additional prior authorization SOURCE: KFF Employer Health Benefits Survey, 2023

(https://www.kff.org/?attachment_id=601870)

Figure 13.22: Among Firms Offering Health Benefits, Percentage of Firms Which Anticipate Taking the Following Actions Over the Next Two Years, 2023

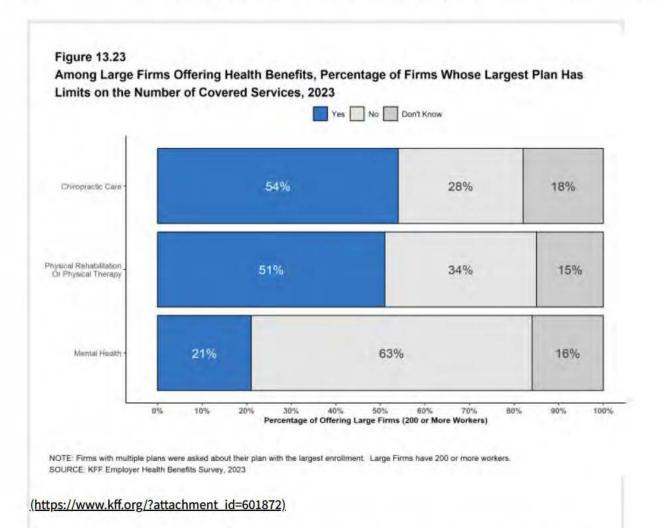


Figure 13.23: Among Large Firms Offering Health Benefits, Percentage of Firms Whose Largest Plan Has Limits on the Number of Covered Services, 2023

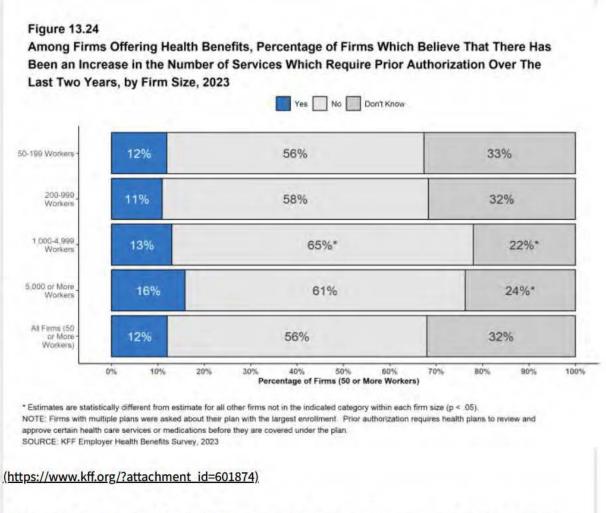


Figure 13.24: Among Firms Offering Health Benefits, Percentage of Firms Which Believe That There Has Been an Increase in the Number of Services Which Require Prior Authorization Over the Last Two Years, by Firm Size, 2023

ABORTION SERVICES

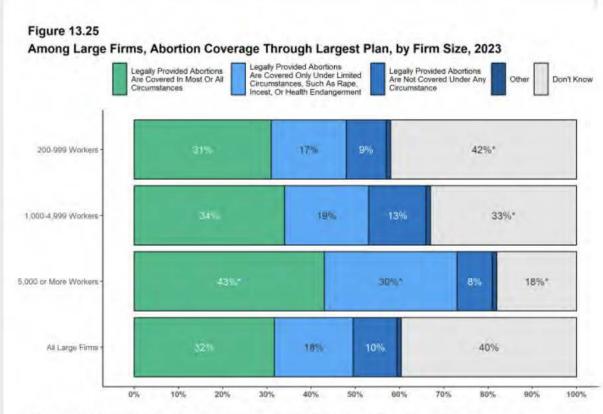
In June 2022, the United States Supreme Court ruled in Dobbs v. Jackson that states could limit the

coverage and delivery of abortion services. This ruling and subsequent state activity to limit access to abortion services has increased public interest in coverage for abortion services in employer plans.

- Large employers (200 or more workers) offering health benefits were asked which of several statements best described coverage of abortion in their largest health plan.
 - Thirty-two percent of these firms said that legally provided abortions are covered in most or all circumstances (sometimes referred to as elective or voluntary abortion). Firms with 5,000 or more workers were more likely than smaller firms to give this reply [Figure 13.25].
 - Eighteen percent of these firms said that legally provided abortions are covered only under limited circumstances, such as rape, incest, or danger to the health or

life of the pregnant enrollee. Firms with 5,000 or more workers were more likely than smaller firms to give this reply [Figure 13.25].

- Ten percent of these firms said that legally provided abortions are not covered under any circumstance [Figure 13.25].
- Forty percent of these responding firms answered "don't know" to this question. Respondents with 200 to 999 workers were more likely than other respondents to answer "don't know" to this question and respondents with 1,000 to 4,999 workers and 5,000 or more workers were less likely to do so [Figure 13.25].
- Large employers offering health benefits also were asked if they or their health plan had taken certain actions related to coverage of abortion following the Supreme Court decision.
 - Among firms that responded that they did not cover legally provided abortion services or covered them only in limited circumstances, 3% of these firms had reduced or eliminated coverage for abortion services in circumstances where they could be legally provided. Firms with 1,000 to 4,999 workers were more likely than larger or smaller firms to make this change [Figure 13.26].
 - Among firms that responded that legally provided abortion services were generally covered, 12% of these firms had added or significantly expanded coverage for abortion services in circumstances where they could be legally provided [Figure 13.27].
- Among large firms offering health benefits, 7% provide, or plan to provide, financial assistance for travel expenses for enrollees who travel out of state to obtain abortion care if they do not have access near their home. Firms with 5,000 or more workers are more likely than smaller firms to say they provide or plan to provide travel benefits for enrollees who travel out of state to obtain an abortion (19% vs. 7%) [Figure 13.28].



* Estimates are statistically different from estimate for all other firms not in the indicated category within each firm size (p < .05). NOTE: Firms with multiple plans were asked about their plan with the largest enrollment. Large Firms have 200 or more workers. SOURCE: KFF Employer Health Benefits Survey, 2023

(https://www.kff.org/?attachment_id=601876)

Figure 13.25: Among Large Firms, Abortion Coverage Through Largest Plan, by Firm Size, 2023

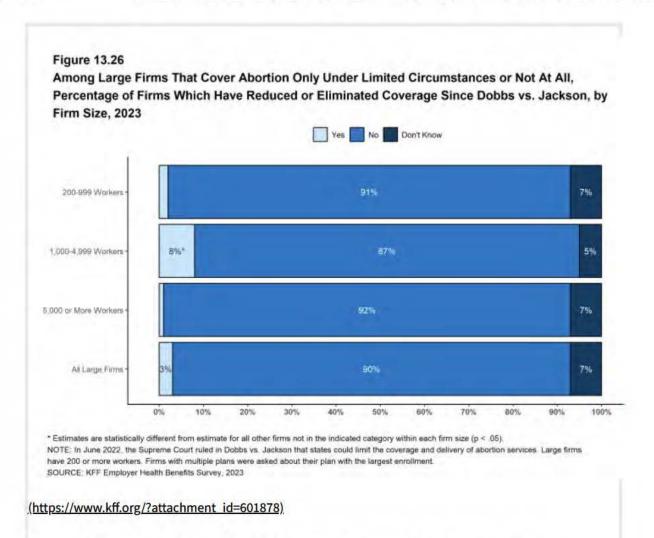
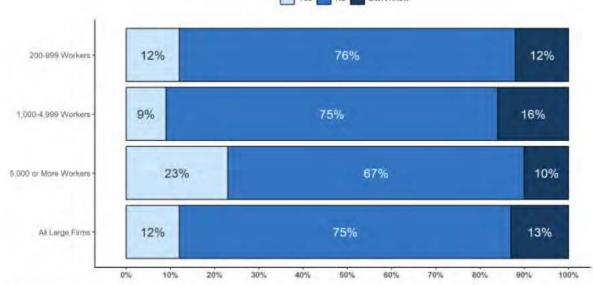


Figure 13.26: Among Large Firms That Cover Abortion Only Under Limited Circumstances or Not at All, Percentage of Firms Which Have Reduced or Eliminated Coverage Since Dobbs Vs. Jackson, by Firm Size, 2023





Tests found no statistical difference from estimate for all other firms not in the indicated category within each firm size (p < .05). NOTE: Large firms have 200 or more workers. In June 2022, the Supreme Court ruled in Dobbs vs. Jackson that states could limit the coverage and delivery of abortion services. Firms with multiple plans were asked about their plan with the largest enrollment. SOURCE: KFF Employer Health Benefits Survey, 2023

(https://www.kff.org/?attachment_id=601880)

Figure 13.27: Among Large Firms That Cover Abortion Services, Percentage of Firms Which Have Added or Significantly Expanded Coverage for Abortion Services Since Dobbs Vs. Jackson, by Firm Size, 2023

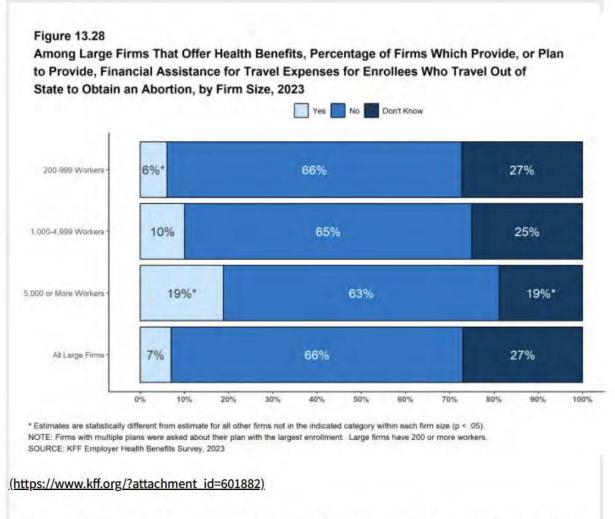


Figure 13.28: Among Large Firms That Offer Health Benefits, Percentage of Firms Which Provide, or Plan to Provide, Financial Assistance for Travel Expenses for Enrollees Who Travel Out of State to Obtain an Abortion, by Firm Size, 2023

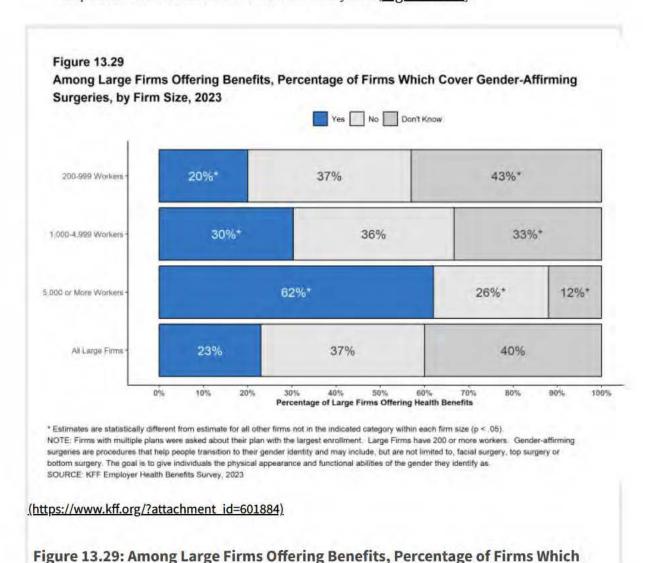
COVERAGE FOR GENDER-AFFIRMING SURGERIES

Gender-affirming surgeries are one component of gender-affirming care, a model of care which includes a spectrum of services aimed at supporting and affirming an individual's gender identity. Gender-affirming surgeries may include, but are not limited to, facial surgery, top surgery, and bottom surgery. Not all transgender or gender nonconforming people elect to have surgery. The purpose of these surgeries is to give individuals a physical appearance and/or functional abilities aligned with their gender identity.

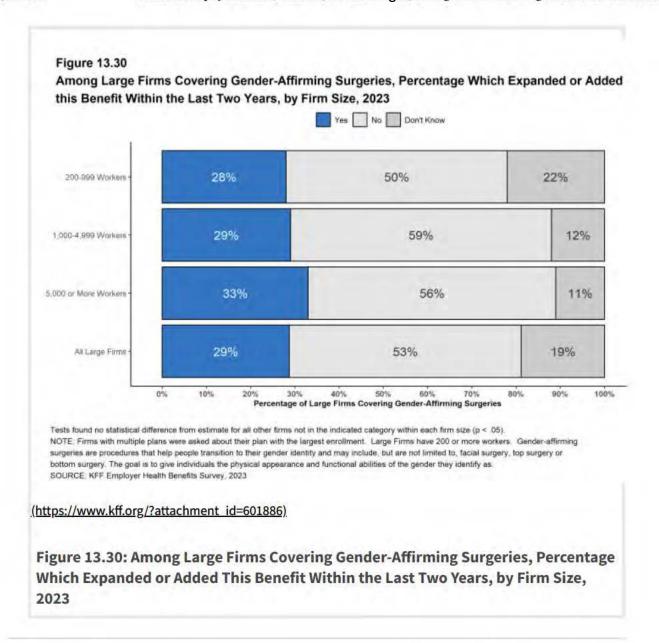
- Among large employers (200 or more workers) offering health benefits, 23% provide coverage for gender-affirming surgery in their largest health plan [Figure 13.29].
 - Firms with 1,000 to 4,999 workers (30%) and firms with 5,000 or more workers (62%) are more likely than firms with 200 to 999 workers (20%) to cover these surgeries [Figure 13.29].
 - Large shares of employers with 200 to 999 workers (43%) and 1,000 to 4,999 workers (33%) answered "don't know" to this question. Among all large firms, 40%

answered "don't know" to this question [Figure 13.29].

- Among firms that offer coverage for gender-affirming surgeries, 29% had added or expanded this benefit within the last two years [Figure 13.30].



Cover Gender-Affirming Surgeries, by Firm Size, 2023



 SECTION 12: HEALTH SCREENING AND HEALTH PROMOTION AND WELLNESS PROGRAMS AND DISEASE MANAGEMENT. (HTTPS://WWW.KFF.ORG/REPORT-SECTION/EHBS-2023-SECTION-12-HEALTH-SCREENING-AND-HEALTH-PROMOTION-AND-WELLNESS-PROGRAMS-AND-DISEASE-MANAGEMENT/)

GET THE LATEST ON HEALTH POLICY

Sign Up For Email Alerts

Enter email address...

SIGN UP >

KFF

© 2024 KFF

Powered by WordPress VIP

CITATIONS AND REPRINTS PRIVACY POLICY

KFF Headquarters: 185 Berry St., Suite 2000, San Francisco, CA 94107 \mid Phone 650-854-9400

 $Washington\ Offices\ and\ Barbara\ Jordan\ Conference\ Center:\ 1330\ G\ Street,\ NW,\ Washington,\ DC\ 20005\ |\ Phone\ 202-347-5270$

www.kff.org | Email Alerts: kff.org/email | facebook.com/KFF | twitter.com/kff

The independent source for health policy research, polling, and news, KFF is a nonprofit organization based in San Francisco, California.

PACT Act Health Care Expanded Eligibility

PRESS RELEASE

March 6, 2024

Print

Butler, PA — On Tuesday March 5, 2024, VA announced that all Veterans who were exposed to toxins and other hazards while serving in the military – at home or abroad – are now eligible to enroll directly in VA health care.

This means that all Veterans who served in the Vietnam War, the Gulf War, Iraq, Afghanistan, the Global War on Terror, or any other combat zone after 9/11 are eligible to enroll in VA health care without first applying for VA benefits. Additionally, Veterans who never deployed but were exposed to toxins or hazards while training or on active duty in the United States are eligible to enroll.

As directed by President Biden (https://www.whitehouse.gov/briefingroom/speeches-remarks/2023/11/11/remarks-by-president-biden-at-a-<u>veterans-day-wreath-laying-ceremony-arlington-va/)</u>, this expansion of VA health care eliminates the phased-in approach called for by the PACT Act – meaning that millions of Veterans are becoming eligible for VA health care up to eight years earlier than written into law. This is a critical step forward because Veterans who are enrolled in VA health care are proven to have better health outcomes than non-enrolled Veterans, and VA hospitals have dramatically outperformed non-VA hospitals in overall quality ratings (https://news.va.gov/press-room/va-outperform-non-va-facilities-cmsratings/) and patient satisfaction ratings (https://news.va.gov/pressroom/nationwide-patient-survey-shows-va-hospitals-outperform-non-vaCase: 24-1714 PACDaguementire Zeraded Eligage: 1/42/1/11/11/11/12/02/14

hospitals/). Additionally, VA health care is often more affordable (https://www.va.gov/health-care/copay-rates/) than non-VA health care for Veterans.

7/24/24, 3:58 PM

VA encourages all eligible Veterans to visit VA.gov/PACT or call 1-800-MYVA411 to learn more and apply for VA health care today. Since President Biden signed the PACT Act into law on August 10, 2022, more than 15,994 Pennsylvania Veterans have enrolled in VA health care.

"If you're a Veteran who may have been exposed to toxins or hazards while serving our country, at home or abroad, we want you to come to us for the health care you deserve," said **VA Secretary Denis McDonough.** "VA is proven to be the best, most affordable health care in America for Veterans – and once you're in, you have access for life. So don't wait, enroll today."

"Today, we're making millions of Veterans eligible for VA health care years earlier than called for by the PACT Act," said VA **Under Secretary for Health Shereef Elnahal, M.D.** "With this expansion, VA can care for all Veterans who served in the Vietnam War, the Gulf War, Iraq, Afghanistan, the Global War on Terror, or any other combat zone after 9/11. We can also care for Veterans who never deployed but were exposed to toxins or hazards while training or on active duty here at home – by working with chemicals, pesticides, lead, asbestos, certain paints, nuclear weapons, x-rays, and more. We want to bring all of these Veterans to VA for the care they've earned and deserve."

"The expanded eligibility means greater opportunity now for Veterans to get the care they have earned and deserve. If you are a Veteran living in Armstrong, Butler, Clarion, Lawrence, and Mercer Counties, I encourage you to reach out to us today to learn about the many programs and services that are available to you," comments Sharon Coyle, Executive Director.

In addition to expanding access to VA care, this decision makes it quicker and easier for millions of Veterans to enroll. Many Veterans believe they must apply to receive VA disability compensation benefits (https://www.va.gov/disability/) to become eligible for VA health care, but this is not correct. With this expansion and other authorities, millions of

Case: 24-1714 PACDagumentire Zepaded Eligage: 1482 ther HEilledire 10/331/2024 7/24/24, 3:58 PM eligible Veterans can enroll directly in VA care – without any need to first apply for VA benefits.

This expansion of care covers Vietnam Veterans, Gulf War Veterans, Iraq War Veterans, Afghanistan War Veterans, Veterans who deployed in support of contingency operations for the Global War on Terror (Operation Enduring Freedom, Operation Freedom's Sentinel, Operation Iraqi Freedom, Operation New Dawn, Operation Inherent Resolve, and Resolute Support Mission), and more (https://www.va.gov/health-care/eligibility/).

This expansion also covers many Veterans who never deployed as a part of a conflict but were exposed to toxins or hazards while serving in the U.S. Specifically, under this expansion of care, any Veteran who participated in a toxic exposure risk activity (TERA) – at home or abroad – is eligible for VA health care. VA has determined that Veterans who were exposed to one or more of the following hazards or conditions during active duty, active duty for training, or inactive duty training participated in a TERA: air pollutants (burn pits, sand, dust, particulates, oil well fires, sulfur fires); chemicals (pesticides, herbicides, depleted uranium with embedded shrapnel, contaminated water); occupational hazards (asbestos, industrial solvents, lead, paints including chemical agent resistant coating, firefighting foams); radiation (nuclear weapons handling, maintenance and detonation, radioactive material, calibration and measurement sources, X-rays, radiation from military occupational exposure); warfare agents (nerve agents, chemical and biological weapons); and more (https://www.publichealth.va.gov/exposures/). VA will use all available information to determine if Veterans participated in a TERA, including military records and service connection.

VA is executing a nationwide campaign to ensure that as many Veterans as possible enroll. To date, VA's PACT Act outreach campaign has included more than 2,500 events nationwide, \$13 million in paid advertising (https://news.va.gov/press-room/va-launches-advertising-campaign-toencourage-new-veterans-to-sign-up-for-health-care-and-benefits/), 88,000 earned media clips, more than 400 million emails and letters to Veterans, VA's first-ever text messaging campaign, the creation of a one-stop-shop PACT Act website (https://www.va.gov/resources/the-pact-act-and-your-va-

Case: 24-1714 PAD QGumentire Z8 22ded EPgage: 1483 tler HEilledire 10/31/2024 7/24/24, 3:58 PM

benefits/), and more. This is the largest outreach campaign in VA history, which has one goal in mind: ensure that all Veterans – and their survivors – get the health care and benefits they deserve under the PACT Act.

For more information about how the PACT Act is helping Veterans and their survivors, visit VA's PACT Act Dashboard (https://www.accesstocare.va.gov/healthcare/pactact). To apply for care or benefits today, visit <u>VA.gov/PACT (https://www.va.gov/resources/the-pact-</u> act-and-your-va-benefits/) or call 1-800-MYVA411. More information on eligibility can be found at VA.gov/PACT (https://www.va.gov/resources/thepact-act-and-your-va-benefits/).

Media contacts

Paula McCarl, Public Affairs Officer 878-271-6492

Paula.McCarl@va.gov

###

See all news releases >

Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA DIRECTIVE 1091 Transmittal Sheet February 18, 2020

PLASTIC RECONSTRUCTIVE SURGERY

- **1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive establishes policy for conducting plastic reconstructive surgery.
- **2. SUMMARY OF MAJOR CHANGES:** The Training and Records Management paragraphs were added. Oversight responsibilities for the Under Secretary of Health and the Deputy Under Secretary for Health for Operations and Management were added.
- **3. RELATED ISSUES:** VHA Directive 1102.01(1), National Surgery Office, dated April 24, 2019 and VHA Handbook 1100.19, Credentialing and Privileging, dated October 15, 2012.
- **4. RESPONSIBLE OFFICE:** The National Surgery Office (10NC2) is responsible for the contents of this directive. Questions may be addressed at 202-461-7130 or referred to vhaconso@va.gov.
- **5. RECISSIONS:** VHA Directive 1091, Plastic Reconstructive Surgery, dated February 21, 2014, is rescinded.
- **6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of February 28, 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE UNDER SECRETARY FOR HEALTH:

/s/ Renee Oshinski
Deputy Under Secretary for Health
for Operations and Management

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution List on February 21, 2020.

February 18, 2020

VHA DIRECTIVE 1091

CONTENTS

PLASTIC RECONSTRUCTIVE SURGERY

1. PURPOSE	1
2. BACKGROUND	1
3. DEFINITIONS	1
4. POLICY	
5. RESPONSIBILITIES	
6. TRAINING	3
7. RECORDS MANAGEMENT	3
8 REFERENCES	3

February 18, 2020 VHA DIRECTIVE 1091

PLASTIC RECONSTRUCTIVE SURGERY

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes the policy for conducting plastic reconstructive surgery. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b); Title 38 Code of Federal Regulations (CFR) 17.38(a)(1)(x).

2. BACKGROUND

- a. Health care services are provided to eligible Veterans by VA consistent with the medical benefits package in 38 CFR 17.38. The medical benefits package specifically includes plastic reconstructive surgery required as a result of disease or trauma and does not include cosmetic surgery that is not medically necessary.
- b. In accordance with 38 CFR 17.38, care referred to in the medical benefits package will be provided to individuals only if it is determined by appropriate health care providers that the care is needed to promote, preserve, or restore the health of the individual and is consistent with generally accepted standards of medical practice. Care is deemed to promote health if the care will enhance the quality of life or daily functional level of the Veteran, identify a predisposition for development of a condition or early onset of disease which can be partly or totally ameliorated by monitoring or early diagnosis and treatment, and prevent future disease. Care is deemed to preserve health if the care will maintain the current quality of life or daily functional level of the Veteran, prevent the progression of disease, cure disease, or extend life span. Care is deemed to restore health if the care will restore the quality of life or daily functional level that has been lost due to illness or injury. **NOTE:** VHA Directive 1341, Providing Health Care for Transgender and Intersex Veterans, dated May 23, 2018, provides information regarding gender affirmation surgery.

3. DEFINITIONS

<u>Plastic Reconstructive Surgery</u>. Plastic reconstructive surgery consists of those surgical procedures performed for the revision of external bodily structures which deviate from normal either from congenital or acquired causes.

4. POLICY

It is VHA policy that plastic reconstructive surgery is performed only for procedures deemed medically necessary.

5. RESPONSIBILITIES

- a. <u>Under Secretary for Health.</u> The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.
- b. <u>Deputy Under Secretary for Health for Operations and Management.</u> The Deputy Under Secretary for Health for Operations and Management is responsible for:

February 18, 2020 VHA DIRECTIVE 1091

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

- (2) Ensuring that each VISN Director has the sufficient resources to implement this directive in all VA medical facilities within that VISN.
- (3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.
- c. **National Director of Surgery.** The National Director of Surgery is responsible for:
- (1) Maintaining a list of all VA medical facilities with the necessary capability to serve as referral centers for plastic reconstructive surgical procedures. This list must be updated quarterly and must be available to all VA medical facilities on the National Surgery Office intranet site available at:

 http://vaww.dushom.va.gov/DUSHOM/surgery/NSOMaps.asp. **NOTE:** This is an internal VA Web site that is not available to public.
 - (2) Providing guidance on the interpretation of this directive.
- d. <u>Veterans Integrated Services Network Director</u>. The VISN Director is responsible for:
- (1) Ensuring that capability exists for providing plastic and reconstructive surgical procedures for patients within the VISN.
- (2) Ensuring that each VA medical facility Director has the sufficient resources to fulfill the terms of this directive in all of the VA medical facilities within that VISN.
- (3) Providing oversight of VA medical facility Directors to assure compliance with this directive, relevant standards, and applicable regulations.
 - e. **VA Medical Facility Director.** The VA medical facility Director is responsible for:
- (1) Ensuring that plastic and reconstructive surgical procedures, either performed in VA medical facilities or in the community, are performed only for medically necessary indications, and that such indications are documented in the patient's electronic health record.
- (2) Ensuring eligible Veterans have access to plastic reconstructive surgery as required by this directive.

NOTE: See VHA Handbook 1100.19, Credentialing and Privileging, dated October 15, 2012, for information regarding qualification standards for providers.

February 18, 2020 VHA DIRECTIVE 1091

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. REFERENCES

- a. 38 U.S.C. 7301(b).
- b. 38 CFR 17.38.
- c. VHA Handbook 1100.19, Credentialing and Privileging, dated October 15, 2012.
- d. VHA Directive 1102.01(1), National Surgery Office, dated April 24, 2019.
- e. VHA Directive 1341(1), Providing Health Care for Transgender and Intersex Veterans, dated May 23, 2018.
- f. National Surgery Office, available at: http://vaww.dushom.va.gov/DUSHOM/surgery/NSOMaps.asp. *NOTE:* This is an internal VA Web site that is not available to public.

In Reply Refer To: **00REG**



Office of General Counsel Washington DC 20420

September 1, 2022

Subject: Regulatory Impact Analysis for RIN 2900-AR57(IF), Reproductive Health Services

I have reviewed the attached Regulatory Impact Analysis and determined the following:

- 1. The Department of Veterans Affairs (VA) has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and has determined that the action is a significant regulatory action under Executive Order 12866.
- 2. This rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601–12.
- 3. This rulemaking is not likely to result in the expenditure of \$100 million or more by State, local, and tribal governments, in the aggregate, or by the private sector, in any one year, under the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.
- 4. Attached please find the relevant Regulatory Impact Analysis document, dated August 29, 2022.

Approved by:

Michael Shores Director Office of Regulation Policy & Management (00REG) Office of General Counsel

(Attachment)

Regulatory Impact Analysis for RIN 2900 - AR57(IF)

Title of Rulemaking: Reproductive Health Services

Purpose: To determine the economic impact of this rulemaking.

Statement of Need: The Department of Veterans Affairs (VA) has determined it needs to amend its medical regulations, in accordance with 38 U.S.C. 501, to ensure that veterans and Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) beneficiaries will be able to obtain abortion counseling and also obtain abortions, irrespective of what laws or policies States and localities may impose, when: (1) the life or health of the pregnant veteran or health of the CHAMPVA beneficiary would be endangered if the pregnancy were carried to term; or (2) the pregnancy is the result of an act of rape or incest.

Summary: VA amends its medical regulations to remove the exclusion of abortion counseling and remove the exclusion of abortion care in certain circumstances for both the medical benefits package available to veterans and the care available to CHAMPVA beneficiaries. From VA's perspective, allowing even one preventable death of a veteran or CHAMPVA beneficiary by limiting access to abortions is unacceptable.

Benefits: The non-financial benefits to veterans and CHAMPVA beneficiaries will be significant. Pursuant to its mission, VA provides veterans with access to needed medical services and CHAMPVA beneficiaries with access to medically necessary and appropriate medical services. As VA explains in this rulemaking, VA has determined that providing access to abortions is needed when the life or health of the pregnant veteran would be endangered if the pregnancy were carried to term or when the pregnancy is the result of an act of rape or incest and is medically necessary and appropriate to protect the health of CHAMPVA beneficiaries, when the health of the CHAMPVA beneficiary would be endangered if the pregnancy were carried to term or when the pregnancy is the result of an act of rape or incest.¹ Providing such abortions and abortion counseling will also promote clarity and parity across federal agencies by making VA's policies more consistent with those of other federal providers that currently provide access to certain abortion services.

The Veterans Health Administration (VHA) serves a particularly vulnerable population when it comes to adverse maternal outcomes. Maternal morbidities and mortality often

¹ See, e.g., Abortion Can Be Medically Necessary, Am. College of Obstetricians and Gynecologists, Sep. 25, 2019. http://www.acog.org/news/news-releases/2019/09/abortion-can-be-medically-necessary (last visited Aug. 22, 2022); see also Elizabeth G Raymond & David A Grimes, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States,

¹¹⁹ OBSTETRICS & GYNECOLOGY 215, 216 (2012); Marian F. MacDorman et al., Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues 128 OBSTETRICS & GYNECOLOGY 447 (2016) (finding a 26.6 percent increase in maternal mortality rates between 2000 and 2014); and Victoria L.Meah, et al., Cardiac output and related haemodynamics during pregnancy: a series of meta-analyses, HEART J., 102:518-526 (2016).

result in higher health care costs, to say nothing of the human costs involved. To the extent that providing abortions and abortion counseling to veterans and CHAMPVA beneficiaries would reduce the rate of maternal morbidity and mortality, VHA could theoretically see a minimal cost benefit due to those improved health outcomes. However, financial impact does not factor into the importance of this regulation for veteran and CHAMPVA beneficiary lives and health.

The rule will not result in a significant benefit to members of the healthcare industry or any other non- VHA entity or individual.

Estimated Impact: VA anticipates transfers of \$2.1 million in Fiscal Year (FY) 2023 and \$11.3 million from FY 2023 through FY 2027 to provide abortion and abortion counseling services to veterans and CHAMPVA beneficiaries, including beneficiary travel. VA has provided these estimates in Table 1 below and further information regarding these obligations is discussed in the Assumptions and Methodology section of this analysis.

Table 1: Total Budgetary Impact (Services)

	Abortion Treatment Expenditures (Thousands)		Beneficiary Travel (Thousands)	Total Expenditures (Thousands)	
Fiscal Year	Cases	Transfers	Transfers	Cases	Total Transfers
2023	1,024	\$931	\$1,151	1,024	\$2,082
2024	1,033	\$976	\$1,196	1,033	\$2,172
2025	1,043	\$1,022	\$1,243	1,043	\$2,265
2026	1,053	\$1,071	\$1,291	1,053	\$2,362
2027	1,061	\$1,118	\$1,342	1,061	\$2,460
5-Year Total	5,213	\$5,118	\$6,223	5,213	\$11,341
2028	1,067	\$1,164	\$1,394	1,067	\$2,558
2029	1,072	\$1,211	\$1,448	1,072	\$2,659
2030	1,074	\$1,255	\$1,505	1,074	\$2,760
2031	1,076	\$1,297	\$1,564	1,076	\$2,861
2032	1,075	\$1,337	\$1,625	1,075	\$2,962
10-Year Total	10,578	\$11,381	\$13,759	10,578	\$25,140

Assumptions and Methodology:

Cost of Abortion Methodology

Utilization Projection

Included in the cost projections is the total number of female veterans enrolled in VA by year based on the 2021 (FY20) Enrollee Health Care Projection Model (EHCPM).

The number of CHAMPVA beneficiaries includes certain spouses, children, survivors, and caregivers of veterans who meet specific eligibility criteria under 38 U.S.C. 1781(a). Spouses were limited to females. Children were limited to those aged 15 and older; gender detail is not known so it is assumed 50 percent of children are female. For caregivers who qualify for CHAMPVA, age and gender information is not known. However, gender information is known for their sponsor, so VA made the following simplifying assumptions: spouses are the same age as the sponsor, children are all under age 25 and 50 percent female, parents are all over age 50 and therefore assumed to have no pregnancy related costs, and siblings and other caregivers are the same age as the sponsor and 50 percent female.

The portion of veterans who would seek an abortion when the life of the pregnant veteran is endangered if the pregnancy is carried to term and the portion of veteran enrollees and CHAMPVA beneficiaries who would seek an abortion when the pregnancy is the result of rape or incest is based on data from the Department of Defense (DoD), which provides abortions in similar circumstances. Based on data from 2013 to 2016, 0.005 percent of active-duty servicemembers of reproductive age had abortions for these reasons. VA assumed the same frequency of these abortions for veteran enrollees and CHAMPVA beneficiaries.

The portion of veterans and CHAMPVA beneficiaries who would seek an abortion when the health of the pregnant veteran or CHAMPVA beneficiary is endangered if the pregnancy is carried to term is based on data reflecting rates of high-risk pregnancies and studies of severe maternal morbidity rates.

VA assumed that all abortions for veterans and CHAMPVA beneficiaries covered under this proposal will be paid for or provided by VA. To the extent that some or all of this care will be paid for by other types of health care coverage, the effect would be a reduced cost for VA.

Cost Projection

The cost of an abortion for veterans who would seek an abortion when the life of the pregnant veteran is endangered if the pregnancy is carried to term or for veterans and CHAMPVA beneficiaries when the pregnancy is a result of an act of rape or incest is assumed to be \$500 in FY 2020. VA assumes a large majority of these abortions will occur early in the pregnancy and will have a relatively low cost. Some abortions may occur late in the pregnancy, resulting in a higher cost, but VA assumes such abortions will be very infrequent.

The cost of an abortion for veterans and CHAMPVA beneficiaries seeking an abortion when the health of the pregnant veteran or beneficiary is endangered if the pregnancy is carried to term is assumed to be \$2,875 in FY 2020. This estimate is based on an assumption that 75 percent of the abortions will be low-cost services with an average cost of \$500 and 25 percent will be high-cost surgical procedures with an average cost of \$10,000.

These costs are increased to reflect medical inflation over time.

This expenditure estimate only reflects the costs associated with abortion treatment. There may be cost avoidance due to a potential reduction in maternity and newborn services. However, the cost avoidance is expected to be minimal.

Cost of Beneficiary Travel Methodology

Based on the assumptions and data above, VA estimates that VA will provide or cover 1000 abortions annually.

Of the 1000 abortions provided or covered annually, VA assumed that 99 percent will occur in the first trimester, consistent with national estimates from the American College of Obstetricians and Gynecologists (ACOG).

VA assumed that of those 990 first trimester abortions, one-half (495) will be medication abortions and will not require overnight travel. VA further assumed that the remaining half (495) of first trimester abortions will be done as abortion procedures. VA assumed that 50 percent of abortion procedures (approximately 250) for veterans will require travel. Travel may include travel to other health care facilities because VA may not have the capability to provide that care at the patient's local facility. It may also include travel for veterans who could previously receive care in the community but must now travel to a VA facility.

Of the 250 veterans who will require travel for abortion services annually, VA estimates that 72 percent will be eligible for beneficiary travel. Eligibility for beneficiary travel is governed by 38 U.S.C. 111 and 38 CFR part 70. Among other criteria, veterans with a service-connected disability rated at 30 percent or more are eligible for reimbursement for travel in connection with VA authorized appointments. Seventy-two percent of current veteran users of VHA who are capable of pregnancy have a service-connected disability rated at 30 percent or more and are thus eligible for beneficiary travel. Therefore, 180 veterans are estimated to use beneficiary travel for first trimester abortions. VA assumes all veterans who travel for abortions may need an attendant.

VA assumed that 1 percent of abortions (10) will occur in the second trimester. VA assumed such abortions will require a special mode of travel to include interfacility travel (e.g., an air ambulance).

Cost Projection

The average cost of beneficiary travel for veterans who would seek an abortion is assumed to be \$1,599.25 per veteran in 2023. The average cost to travel for veterans' attendants is assumed to be \$2,019.00 per attendant in 2023. The average cost for special mode travel is assumed to be \$50,000 per veteran in 2023.

Paperwork Reduction Act: This rulemaking contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–21.

Alternative Policy Approaches: An alternative policy approach would have been to issue a notice of proposed rulemaking, but VA has found good cause to publish this rule without prior opportunity for public comment, with an immediate effective date, and with a comment period running thirty days from publication in the Federal Register. In Dobbs v. Jackson Women's Health Organization, 142 S. Ct. 2228 (2022), the Supreme Court overruled constitutional protections recognized in Roe v. Wade, 410 U.S. 113 (1973), and Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992). Numerous States have responded by enforcing restrictions on abortion that have made, and will likely continue to make, it very difficult for many veterans and CHAMPVA beneficiaries to receive abortions in their communities, creating urgent health risks to them. It is critical that this rule be published and effective immediately to ensure pregnant veterans and CHAMPVA beneficiaries have access to this important care. There are no appropriate alternatives to issuing an interim final rule in this instance.

Submitted by:

Shereef Elnahal, M.D., M.B.A. Under Secretary for Health, Department of Veterans Affairs

Date: August 29, 2022

Second Amended Index of Record of Department of Veterans Affairs' February 22, 2024 Denial of Petitioner's Rulemaking Petition

- 1. Petition for Rulemaking to Promulgate Regulations Governing Provision of Sex Reassignment Surgery to Transgender Veterans, with attachments, May 9, 2016.
- 2. U.S. Department of Veterans Affairs, RIN 2900-AP69, "Removing Exclusion of Gender Alterations from the Medical Benefits Package," Spring 2016.
- 3. Letter from Members of Congress to the Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, June 22, 2016.
- 4. U.S. Department of Veterans Affairs, "Economic Impact Analysis for RIN 2900-AP69, Removing Gender Alterations Restriction from the Medical Benefits Package," July 29, 2016.
- 5. Letter from Members of the House of Representatives to the Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, September 12, 2016.
- 6. Letter from Members of the Senate to the Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, September 22, 2016.
- 7. Letters from the Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, to Members of Congress, November 10, 2016.
- 8. Petition for Rulemaking and Request for Comments, 83 Fed. Reg. 31711, July 9, 2018.
- 9. Public Comments to Petition for Rulemaking and Request for Comments.
- 10. The American College of Obstetrician and Gynecologists, "America's Frontline Physicians Urge Trump Administration to Protect Transgender Patients and Women's Reproductive Health," May 28, 2019.
- 11. Message from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Employees, U.S. Department of Veterans Affairs, February 23, 2021.

- 12. Memo from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, "Services for LGBT Beneficiaries and Employees," February 23, 2021.
- 13. The Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, "Decision Memorandum: Removal of Gender Alterations Exclusion from VA Medical Benefits Package," June 11, 2021.
- 14. Remarks by the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, Orlando Veterans Affairs Healthcare System's 11th Annual Pride Month Celebration, June 19, 2021.
- 15. Remarks by the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, 99th Disabled American Veterans Annual Convention, July 31, 2021.
- 16. Entry RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs, Fall 2021.
- 17. Entry RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs, Spring 2022.
- 18. Press Release, U.S. Department of Veterans Affairs, "VA National Pride Month Kickoff," June 1, 2022.
- 19. Conclusion of EO 12866 Regulatory Review, RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs, September 7, 2022.
- 20. Entry RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs, Fall 2022.
- 21. Message from Transgender American Veterans Association to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, January 12, 2023.
- 22. Letter from Members of Congress to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, January 27, 2023.

23. Letter from Veteran Advocacy Groups to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, January 30, 2023.

- 24. Remarks by the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Disabled American Veterans, February 26, 2023.
- 25. Letter from Kimberly M. Mitchell, Director, Veteran Service Organization Liaison, U.S. Department of Veterans Affairs, to Transgender American Veterans Association, March 6, 2023.
- 26. Letter from Kimberly M. Mitchell, Director, Veteran Service Organization Liaison, U.S. Department of Veterans Affairs, to Minority Veterans of America, March 8, 2023.
- 27. Letters from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Members of Congress, March 21, 2023.
- 28. Letter to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, March 31, 2023.
- 29. Entry RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs, Spring 2023.
- 30. Letter from Members of the House of Representatives to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, March 31, 2023.
- 31. Letter from Kimberly M. Mitchell, Director, Veteran Service Organization Liaison, U.S. Department of Veterans Affairs, to Minority Veterans of America, May 2, 2023.
- 32. Letters from Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Members of Congress, May 9, 2023.
- 33. Remarks by the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, Press Conference, June 27, 2023.
- 34. Statement to the United States Senate Committee on Veterans' Affairs, Shereef Elnahal, Under Secretary for Health, U.S. Department of Veterans Affairs, and

- Joshua D. Jacobs, Under Secretary for Benefits, U.S. Department of Veterans Affairs, "PACT Act Implementation," July 26, 2023.
- 35. Entry RIN 2900-AR34, Unified Agenda, Office of Information and Regulatory Affairs, Fall 2023.
- 36. Letter from Michael Wishnie, Counsel, Transgender American Veterans Association, to Richard J. Hipolit, Acting General Counsel, U.S. Department of Veterans Affairs, November 20, 2023.
- 37. Letter from Richard J. Hipolit, Acting General Counsel, U.S. Department of Veterans Affairs, to Counsel, Transgender American Veterans Association, December 22, 2023.
- 38. Letter from Michael Wishnie, Counsel, Transgender American Veterans Association, to Richard J. Hipolit Acting General Counsel, U.S. Department of Veterans Affairs, with attachments, January 16, 2024.
- 39. Petition for Writ of Mandamus to the Department of Veterans Affairs, January 25, 2024.
- 40. Letter from Members of the House of Representatives to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, February 1, 2024.
- 41. U.S. Department of Veterans Affairs, "The Pact Act and Your VA Benefits," https://perma.cc/5XXA-95SF.
- 42. U.S. Department of Veterans Affairs, "Accessing PACT Act Benefits and Services," https://perma.cc/J47H-ZMSE.
- 43. U.S. Department of Veterans Affairs, "PACT ACT Performance Dashboard," https://perma.cc/G8UJ-TX8E.
- 44. Memorandum from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Under Secretary for Health, U.S. Department of Veterans Affairs, "Analysis of Amendment to 38 C.F.R. § 17.38(c)(4) and PACT Act Eligibility," February 22, 2024.

45. Letters from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to Counsel, Transgender American Veterans Association, February 22, 2024.

- 46. Letter from Members of Congress to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, June 28, 2021.*
- 47. Letter from Members of Congress to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, July 15, 2021.*
- 48. Letter from the Honorable Barry Loudermilk, Member of Congress, to the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, August 11, 2021.*
- 49. Letter from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to the Honorable Matthew Rosendale Sr., Member of Congress, September 7, 2021.*
- 50. Letter from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to the Honorable Jack Bergman, Member of Congress, September 8, 2021.*
- 51. Letter from the Honorable Denis McDonough, Secretary, U.S. Department of Veterans Affairs, to the Honorable Barry Loudermilk, Member of Congress, September 21, 2021.*